OPTN Pancreas Transplantation Committee
Meeting Summary
November 1, 2022
In-person and Conference Call

Rachel Forbes, MD, Chair
Oyedolamu Olaitan, MD, Vice Chair

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met in Chicago, IL and via Citrix GoToMeeting teleconference on 11/1/2022 to discuss the following agenda items:

1. Vice Chair Opening and Process
2. Update: Continuous Distribution of Kidneys and Pancreata
3. Organ Allocation Simulation (OASIM) Results Presentation
4. Massachusetts Institute of Technology (MIT) Tradeoff Curves Presentation
5. Workgroup Updates
6. Closing Remarks

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

1. Vice Chair Opening and Process

UNOS staff presented information on the Vice Chair position and the nomination and selection process to the Committee.

Presentation summary:

UNOS staff outlined the goals of the nomination and selection process:

- To increase transparency in the selection process
- To promote inclusiveness
- To ensure thorough review and vetting of candidates

UNOS staff sent out a call for interest the week prior to this meeting and reminded any interested members to submit interest by November 4, 2022. The timeline of the process was explained, with finalist candidates submitted to the OPTN Vice President in January for final appointment. In addition to the standard preferred OPTN Committee Vice Chair qualifications, the following pancreas-specific preferred qualifications were included:

- Knowledge of continuous distribution
- Experience in pancreas donation and transplantation
- Strong advocate for pancreas transplantation
- Appointment consideration open to all backgrounds and disciplines

Summary of discussion:

There was no further discussion.

Next steps:

Any additional interested candidates will submit their interest to staff by November 4, 2022.

2. Update: Continuous Distribution of Kidneys and Pancreata

Staff provided an update on Public Comment Feedback on the Kidney-Pancreas Continuous Distribution (KP CD) framework and Kidney Allocation System (KAS250).

KP CD Public Comment Feedback:

Presentation summary:

UNOS staff explained that 32 comments were received in total and explained trends and suggestions found from analysis. Regarding the Analytic Hierarchy Process (AHP) exercise used to collect community feedback on attributes, there were some concerns about underrepresentation of certain groups, weight placed on prior living donor and pediatrics, and comments emphasizing the importance of distance and waiting time for pancreas allocation. Another trend seen was support for current and additional modeling efforts, especially regarding pediatric and sensitized candidates and the use of predictive analytics.

Regarding medical urgency, comments were received about how medical urgency will or will not be incorporated into KP CD for pancreas and the potential to include diabetic patients in medical urgency due to increased diabetic mortality rates on dialysis. For waiting time, commenters demonstrated support for the waiting time rating scale being kept linear. There was a suggestion to reinstate waiting time for a failed kidney after Simultaneous Kidney-Pancreas (SPK) if the kidney is lost within the first 60-90 days.

Commenters demonstrated support for prioritization of pediatric candidates, interest in the interaction between kidney-pancreas and kidney allocation and the potential impact on pediatric access, and concern that SPK prioritization may impact pediatric access to kidneys. Regarding prior living donor priority, there was support for priority for all living donors and a concern that prior living priority might be altered or lost in the transition to KP CD. Other themes mentioned included equity, cold ischemic time, efficiency considerations, the proximity efficiency rating scale, and system tools and resources.

Summary of discussion:

There was no discussion.

KA250 Public Comment Feedback:

Presentation Summary:

UNOS staff explained the following trends received from analysis of the public comment feedback on KAS250:

- Satisfaction in the improvement among minorities and high Calculated Reactive Panel Antibody (CRPA) candidates
- The increase in transplant could be due to various factors
- Concern for the current discard rate and the discard rate transitioning to KP CD
- Need for a better understanding of KAS250 and effects of transplant rates, discards, and logistics before transitioning to KP CD
- Lessons learned from KAS250 should be incorporated into KP CD

Summary of discussion:

A member brought up concerns regarding candidate factors and discard rates in the transition to continuous distribution. The Vice Chair answered that the new rating scale for placement efficiency in continuous distribution should help pancreata stay local.

3. Organ Allocation Simulation (OASIM) Results Presentation

The Committee received a presentation on Scientific Registry of Transplant Recipients (SRTR) OASIM modeling results following the release of the formal analysis report.

Presentation summary:

SRTR staff described the background and details of the data request. Two scenarios for pancreas were modeled. Staff described details of the new OASIM as a change from the original Simulated Allocation Model (SAM) to update software to allow more flexibility for future modeling. The method used for simulating remains the same between the two models.

The aim of this OASIM modeling is to use historical data to ask what would have happened to the historical cohort under different allocation policies. SRTR staff cautioned that the simulations cannot predict future events. SRTR described details of the simulation sub-models, explaining randomized arrivals for donors and history generation for candidates. Individuals who were transplanted in real life may or may not receive a transplant in the simulation, depending on allocation policies. Regression modeling was used for placement mechanism, post-transplant survival, and organ acceptance. A 1-year cohort was used to model allocation. A 15-year cohort from 2007 to 2021 was used for modeling post-transplant graft and patient survival. Committee members were reminded of the formula for score calculation.

SRTR staff explained the rating scales for pancreas Continuous Distribution.

- Candidate Biology:
    - Blood type: a binary score where identical blood types are given a score of 1 and compatible blood types are given a score of 0
    - CPRA: according to the formula set by the committee, with more points given to more sensitized candidates
- Patient Access:
    - Pediatric: a binary score where candidates under 18 receive a score of 1 and all other candidates receive a score of 0
    - Prior living donor: a binary score where prior living donors of any organ receive a score of 1 and all other candidates receive a score of 0
    - Qualifying time: points according to a piecewise linear function of qualifying time
- Placement efficiency
    - Proximity efficiency: points calculated according to a piecewise linear function of distance from donor hospital
    - Whole pancreas: a binary score, where whole pancreas candidates receive a score of 1 and all other candidates receive a score of 0

SRTR explained the different scenarios modeled to the committee, focusing especially on Combined Analytic Hierarchy Process (AHP) Weights and All Donor Efficiency Weights. The other two scenarios modeled had the same weights as the Combined AHP Weights scenario. Donor modifiers were explained: whole pancreas candidates with an age greater than 45 or a donor Body Mass Index (BMI) greater than 30 receive a -1 for whole pancreas, whereas all other candidates receive a 1. This is the only relevant difference in donor weight modifiers modeled.

SRTR staff explained that current policy is modeled to show a baseline. The accepted current practice of offering both kidney and pancreas to the complete kidney-pancreas (KP) match run before offering the kidney to the kidney-alone match run was used in modeling.

The Committee was shown the candidate cohort count by age at listing, candidate blood type, and donated organs by blood type. Groups with low cohort counts, such as the KP and pancreas alone for age 65-90 and blood type AB, were pointed out as a reason for outliers in the modeling. Transplant rate and time to transplant were used to tune the simulation models. SRTR staff then listed the transplant rate grouping and analysis metrics examined in the report.

Data Summary

SRTR staff then presented the results.

- The updated OASIM appears to be an improvement over the existing KPSAM without compromising any functionality.
- The All Donor Efficiency scenario is associated with a significant decrease in travel distance without major changes in other outcomes.
- Older candidates (65 years and older) see a relative increase in transplant rates in all scenarios, more so in the All Donor Efficiency scenario.
- Blood type AB appears to be associated with decreased transplant rates in all scenarios, less so in the All Donor Efficiency scenario.

Summary of discussion:

A member asked how the SRTR determined the validation cohort and the training cohort for modeling. SRTR staff answered that the training and validation cohorts were selected using an 80 percent random sample of the 15-year cohort. A member asked if multi-visceral transplants were included in pancreas cohort counts. SRTR staff answered that kidney-pancreas and pancreas transplants were modeled together. This member then asked about the high Kidney Donor Profile Index (KDPI) group modeled for kidney, and SRTR staff explained that if a kidney greater than KDPI 85 percent shows up on a match run, that kidney is allocated according to the All Donor Efficiency Weights scenario, but this is handled via a donor modifier.

Another member asked if kidney and pancreas rating scales for blood type were different. SRTR staff answered that the rating scales differed, as kidney had different points given to each blood type group. This member then asked if wait time is shown according to race, as there is concern that minority groups may be disadvantaged with the rating scale. SRTR staff answered that some of the data is broken out by race and that the qualifying time rating scale modeled was the one provided to the SRTR by this Committee. The Chair then asked if the 5-year cut off for the linear piecewise function in qualifying time also applied to kidney. Kidney used a different rating scale where candidates could earn above 100 percent, with 100 percent achieved at ten years waiting. The Vice Chair added that for most KP transplants, the average waiting time is within the 3–5-year range. An SRTR staff member added that the chosen weights and rating scales for qualifying time are a product of various Workgroup decisions. The Committee and SRTR staff then discussed the goal of Continuous Distribution as moving away from hard boundaries, both in waiting time and in geography. UNOS staff clarified that Continuous Distribution is aimed at having a standardized approach across organs to allocation, not necessarily deciding more or less emphasis on geography or waiting time.

The Committee discussed a desire to see pancreas-alone modeling without inclusion of multi-visceral organs. SRTR staff responded that this could be included in future modeling, but because cohort numbers for pancreas-alone are usually very low, modeling is more difficult. This also applies for older candidates, due to low cohort numbers. The Chair asked why the graphs shown for pediatric pancreas and KP transplant rates jump from .08 for current policy to about .20 in the modeled scenarios. UNOS staff answered that the boost seen in the modeling is probably due to the added weight included in the pediatric attribute.

A member asked about the high KDPI scenario, noting that the decrease in travel time expected for older candidates is not seen. SRTR staff answered that the high KDPI scenario would apply in kidney transplants only, which is why the decrease is not seen for pancreas. This member further elaborated a concern that travel time is not telling the full story of organ quality. Because recent data shows that although travel time did not significantly increase, cold ischemic time (CIT) is increased, suggesting that time to placement may be the critical factor. This member asked if estimated CIT could be modeled. SRTR staff answered that because modeling is limited to factors known at the time of the match run, distance is the best proxy for CIT.

A member asked about inclusion of discard rates, as this may significantly impact transplantation rates. SRTR staff responded that discard rates are difficult to model and not included in the OASIM.

A member asked about the definition of graft failure used in the simulation. SRTR staff answered that graft failure was modeled according to reporting, not according to definition. A UNOS staff member asked if graft failure for kidney-pancreas (KP) was modeled as either organ separately or failure of both organs. SRTR staff said that just pancreas graft failure was graphed. The Vice Chair added that he thought that the SRTR does not report pancreas graft failure. SRTR staff answered that although graft failure has not been reported in their annual report since 2011, it is included here for modeling. The SRTR will resume reporting pancreas graft failure using the new definition for their annual report this year. The Chair asked if the SRTR knew how well-reported graft failure is, and SRTR staff responded that missing insulin dose data is a limiting factor for reporting.

The Vice Chair described a concern that in the new modeling, very high calculated panel reactive antibody (CPRA) candidates may be disproportionately advantaged, noting public comment feedback on this topic. SRTR staff responded that this is not necessarily suggested by the modeling, and that the public comments are referring to kidney, not pancreas.

Regarding Human Leukocyte Antigen (HLA) DR mismatch by race, one member pointed out that although the data showing relative equity between scenarios is promising, it does assume that candidates made it to the list in the first place, a known area for inequity. A member asked if the SRTR could further graph DR mismatch by race to include 0, 1, and 2 DR mismatches. This is included in the supplemental report, and SRTR staff explained that there is not significant difference between the scenarios for any DR mismatch group.

A member asked if the SRTR looked into transplant rates by size of program. This was not modeled, but this could be included for future requests. Regarding transplant rates in metropolitan versus rural areas, one member commented that it is surprising not to see a difference among the scenarios. SRTR staff answered that this is probably due to the time it takes to prepare the candidate for transplant and time to transplant center. A member expressed confusion on the distance metric. SRTR staff explained that the distance refers to the distance from the donor hospital to the transplant center.

Regarding blood type AB, a member commented that the drop in transplant rates for this group may be less in reality than shown in the modeling. The blood type rating scale, identical over compatible, probably impacted data shown for AB. The AB group also has a low cohort number, which could also explain some variation in the model. SRTR staff explained that if the Committee is interested in further augmenting transplant rates for AB, this could be included in a further modeling request and handled via weights for CPRA and zero DR mismatches.

A member expressed a desire for more data stratified by ethnicity to account for Hispanic candidates included in the White racial group. The Vice Chair commented that behavior (not included in the modeling) may account for the higher transplant rates seen for the 65 and older age group. A member

then asked about body mass index (BMI) data. SRTR staff responded, explaining the donor modifier, and said that BMI data was not modeled in this request.

A member asked if overall transplant rates increased for any of the modeled scenarios. SRTR staff responded that due to the high turndown rate, it is difficult to model increased transplant rates. One member asked if the rate of transplant and observed discard rate corresponds to the rate of listing. The SRTR responded that the makeup of the list affects behavior, which cannot be appropriately modeled.

The Committee discussed a desire to investigate behavior further to provide more information about regional behavior differences. SRTR staff responded that modeling focused on differences among subgroups, so behavior and transplant rate were necessarily constants in the model. The Chair asked if it was possible to include facilitated pancreas in the model, and the SRTR answered that because the model needs an exact set of rules to follow, it will be difficult to incorporate it given current facilitated pancreas policy and trends. The Committee discussed the possibility to standardize and mandate facilitated pancreas, and several members stated that absent relevant data, there would be pushback. SRTR staff added that facilitated pancreas offers are aimed at improving efficiency, and one way to include this in the modeling may be to increase weight on donor placement efficiency. The Committee and SRTR staff discussed the difficulty in modeling the pancreas waiting list, turn down rates, and transplant outcomes due to the highly variable groups that make up the list: pancreas-alone, kidney-pancreas, and pancreas-after-kidney. The Committee discussed center-level behavior, which may impact the data.

One member suggested looking at trends from top-performing centers and lower performing centers to compare. The Chair responded that factors like center comfort and expertise impact gradients in performance, but there are complex factors impacting pancreas donation, recovery, and transplantation. There are many factors impacting access to pancreas, but the SRTR is not able to model beyond the attributes included here for this round of modeling. Factors such as willingness of centers to send surgeons to recover, local recovery and comfort/expertise in pancreas recovery, efficiency of couriers, and willingness to share charters could be discussed further as a separate project.

The Chair asked which modeled scenario is closest to current policy, and SRTR staff answered that both modeled scenarios are similar to current policy in all outcomes except a few, as described in the report. The Committee discussed priorities and pain points, and the SRTR explained the Committee could include all of these thoughts in the next modeling request. The Vice Chair expressed a desire to model a combination of Combined AHP and All Donor Efficiency in the next modeling.

SRTR staff summarized: pancreata have a greater chance of utilization given a shorter travel distance and lower CIT. The analysis suggests that significant improvements can be made in reducing travel distance without compromising other primary metrics. UNOS staff added that ideally, modeling would show a scenario that perfectly reflects the Committee's priorities. However, the most important thing to consider in this modeling is if the model behaved as expected and demonstrated ability to impact key metrics. Results from the modeling show this is the case. The Chair commented that it is difficult to interpret this data because of the low availability of pancreas-only data, and that high emphasis was placed on efficiency to model realistic improvements to the system. The Chair expressed confusion on the interplay between the Pancreas Committee's decision making and impacts on kidney allocation. SRTR staff explained that the modeling was based on existing KP policy. The Vice Chair added that the MOT Committee will be looking at impacts on the kidney list from other organ's policies.

The Chair suggested that it may be helpful to hold webinars on the modeling results to provide the results for both kidney and pancreas to the community, and other members and UNOS staff agreed.

<u>Next Steps:</u>

The Committee will further discuss the modeling results and public comment feedback and provide input to the SRTR on the next modeling run with a data request by the end of December. The SRTR will exclude the redundant scenarios in future requests, take out the combined multi-visceral transplants, and further model AB blood group transplants as part of this.

4. Massachusetts Institute of Technology (MIT) Tradeoff Curves Presentation

The Committee received a presentation on the MIT tradeoff curves results.

Presentation summary:

MIT staff introduced themselves and the background of the project. This modeling request used mathematical optimization and artificial intelligence to aid decision making about continuous distribution policy development, with specific emphasis on attribute weights. The modeling will help the Committee decide on attribute weights for the next round of SRTR OASIM modeling and show what MIT is capable of modeling.

MIT staff briefly introduced their methodology: using the Kidney-Pancreas Simulation Allocation Model (KPSAM) framework and internal software, specific outcomes or objectives are modeled and optimized. This allows the generation of tradeoff curves, such that by tweaking the desired outcomes, the effect on other outcomes can be seen. For example, MIT could look at the relationship between broader geographic distribution and access disparities. This is accomplished by stating desired outcomes in terms of an objective and specific constraints relative to current policy and using 2019 KPSAM to verify. The 2017 transplant cohort is used for this modeling. Directionally, OASIM and MIT modeling agree, giving confidence to both.

Data Summary

MIT showed a graph demonstrating a tradeoff curve of median transplant distance in nautical miles (NM) and disparity in transplant rates, measured using the standard deviation from the original transplant rate. The top of the graph shows the proximity weight associated with each policy. Current policy is shown as a metric of comparison. Staff explained that the graph demonstrates that a policy can be made to reduce geographic disparity without increasing distance, due to the higher level of flexibility that Continuous Distribution provides and the optimization provided by the model. The graph can show a “sweet spot” or inflection point where the maximum benefit can be obtained without negative consequences on the other modeled factor, and the range that policies can take on the specified metrics based on fixed or varying attribute weights.

MIT demonstrated another possible analysis of 50,000 different polices and their impact on transplant by blood group, showing that as the weight on blood type increases, the disparity among blood groups goes down.

MIT explained that tradeoff curves are one way to visualize this analysis, but they have also been working on a data dashboard to allow for more dynamic and robust visualization. The dashboard includes a policy optimizer (which looks like the tradeoff curves previously shown and reports individual attribute weights for a given policy) and a policy analyzer (which allows users to input a policy and see predicted results and outcomes relative to other policies). The dashboard also shows disparity metrics. This tool is currently in progress, but should be available for Committee use soon.

Summary of discussion:

A member asked if MIT is able to model discard rates. MIT staff responded that they can analyze discard rates, but that because they are relying on KPSAM software, changing attribute weights does not seem to impact discard rates significantly.

The Chair asked if this presentation was an example showing what MIT can model. MIT staff responded that yes, the graphs shown represent an example of the metrics MIT can analyze and do not use the most updated cohort used by OASIM in the SRTR's presentation. However, MIT staff explained that if they were to use the more updated cohort, the outcomes would agree directionally. The Chair asked if it was correct to interpret the first graph as suggesting that beyond a weight of 12 percent on proximity efficiency, benefits are not maximized. SRTR staff answered that it is more appropriate to concentrate on median transplant distance because the attribute weight varies depending on the factors modeled. The Vice Chair asked if other factors and attribute weights are held constant for the tradeoff curves presented. MIT staff responded that in the minimization curve, all other factors are tweaked to allow a minimization of the standard deviation of geographic disparity. In the maximization curve, all factors are allowed to vary. If the Committee were to add additional constraints, the two curves would become closer together because there would be less room to vary. Depending on the number of additional constraints, the Committee may end up with only a handful of policies to consider. The Vice Chair asked if the impact of proximity weight on transplant rate across blood groups could be shown to inform decision making about the AB blood type, and MIT responded that they could model this.

SRTR staff expressed confusion that the MIT tradeoff curve does not correlate with SRTR modeling for proximity efficiency, because in order to achieve a median distance of 111 NM, a proximity weight of 30 percent was required. MIT staff answered that in continuous distribution, a reduction in geographic disparities is possible due to the lack of hard constraints in policy, which is why a reduction in standard deviation is seen. The graph only shows KP patients, and SRTR staff posited that the low attribute weight could be caused by this, because solitary pancreata tend to travel further. MIT added that because the two modeling efforts used different cohorts, this could account for some of the differences, even though the models directionally agree.

The Chair asked if this model assumes that transplant rate stays the same, and MIT staff answered yes. The Chair then asked if MIT could model the best policies to increase transplant volume. MIT staff responded that a limitation of using the SRTR model is not being able to draw conclusions from increasing transplant rates due to how their models work. UNOS staff clarified, adding that it is not appropriate to draw conclusions about increasing transplant rates from either OASIM or the tradeoff curves. A member added that what the MIT modeling shows is where behavior converges but not how many centers are doing transplants within the set constraints. MIT staff clarified, stating that a constraint of their modeling was to keep transplant rates at least as good as current policy. Overall transplant rates cannot be changed, however, showing changes in transplant rates of individual subgroups as a result of changing attribute weights is a goal of this analysis.

The Vice Chair stated that because one of the goals of the OPTN is increasing transplant rates, it is difficult to interpret these results in light of that goal. MIT staff responded that although they cannot model transplant rates itself, the Committee could look at using proxies, such as immediate transfer distance, that will necessarily have an impact on transplant rate. A member discussed wanting to adjust for increased donation rates. A member asked if the Committee can safely say that based on the OASIM and MIT results that a proximity efficiency weight of 30 percent is too high. SRTR staff said this may not be a reasonable conclusion because MIT did not show solitary pancreas transplants in their modeling. A member asked if, when the Committee comes up with its desired attribute weights for the second round of modeling, data will be available regarding the actual number of transplants anticipated in the new policy. SRTR responded, explaining that the assumption of a constant rate of overall transplants is built into the model and that obtaining this data would require a different approach to the study. Because the OASIM and KPSAM are built on historical information, these models are reliant on data collected at the time of the offer and offer acceptance is limited to offers that look like historically accepted offers.

The Chair asked if the OPTN Lung Transplantation Committee (Lung Committee) used this modeling to help set attribute weights in Continuous Distribution. MIT staff confirmed that the Lung Committee used this analysis to inform decisions relating to optimizing mortality. UNOS staff clarified that the graphs are best used by Committee members to determine policies that maximize desired outcomes and minimize unwanted outcomes.

An SRTR staff member asked that for the "cloud" analysis, if the upper border corresponds to the maximized curve and the lower border corresponds to the minimized curve. MIT staff answered that this is a correct interpretation.

SRTR and UNOS staff explained that there will always be limitations in the modeling, but that the Committee should use the MIT and OASIM results to make informed decisions about a transition to Continuous Distribution. A member asked how locked in the Committee is once an attribute weight is decided on. UNOS staff explained that an improvement seen in continuous distribution is the ability to modify weights relatively easily and quickly before implementation. A member suggested comparing modeled policies to pre-coronavirus infectious disease (COVID) trends to get a full picture of the data.

A member discussed about some of the metrics shown on the dashboard, such as race, and asked if these things matter. The Chair explained that these are shown to ensure that policies do not accidentally create unintended disparities.

Next Steps:

Committee members can provide additional suggestions regarding analysis metrics to the MIT team via email. MIT will continue working on the dashboard to have it ready for the Committee in the near future.

5. Workgroup Updates

Kidney-Pancreas (KP) Utilization Considerations Workgroup

A member of the Workgroup provided an update on progress and discussions.

Presentation summary:

The KP Utilization Considerations Workgroup focuses on the aspects of kidney and pancreas allocation that fall outside of the composite allocation score (CAS) while transitioning to Continuous Distribution. The Workgroup will discuss topics such as dual kidney allocation, minimum acceptance criteria (MAC) screening, and facilitated pancreas and provide suggestions and recommendations for the Kidney and Pancreas Committees.

The presenter recapped Workgroup discussions to date, explaining that currently, the Workgroup is discussing operationalization of dual kidney allocation, and soon will discuss national kidney offers and operationalization of the kidney minimum acceptance criteria screening tool.

Regarding facilitated pancreas, the presenter explained the Committee's recommendation to the Workgroup:

- Organ Procurement Organizations (OPOs) and the OPTN are permitted to make facilitated pancreas offers if no offer has been accepted 5 hours prior to the scheduled donor organ recovery.
- Bypasses will apply to KP and pancreas candidates.
- All candidates at non-facilitated programs, regardless of CPRA or ABDR mismatch, will be bypassed.

- Bypasses will apply to candidates registered at transplant hospitals more than 100 NM away from the donor hospital.

The Workgroup discussed these recommendations and was supportive of them, with one additional recommendation: alignment between the distance used in bypassing and the distance used in qualifying criteria.

The presenter recapped current policy on released organs and the Workgroup's current recommendations:

- For kidney, the host OPO would have the option to continue allocation according to the original match run or use a released kidney match run, using the location of the kidney when it is released. The released kidney match run would have an increased placement efficiency weight.
- For pancreas, KP, and islets, the Workgroup recommends maintaining current policy.

The next steps for the Workgroup include finalizing recommendations for dual kidney and beginning discussions on National Kidney and the Kidney Minimum Acceptance Screening Criteria.

Summary of discussion:

The Chair asked for clarification on the 100 NM criteria, and the presenter explained that that recommendation only includes facilitated pancreas offers outside 100 NM, not non-facilitated. UNOS staff member clarified that the recommendation of aligning the distances was to reduce center confusion of if accepting a facilitated pancreas offer will count towards the qualifying criteria or not. A member added that the language in the recommendation for alignment is confusing.

A member asked if the recommended framework allows a program who is not currently a facilitated pancreas program to become one after the fact, adding that there should be a method for centers to do this with testing methods. The presenter explained that the Workgroup discussed this and the qualifying criteria is pending. Members discussed the possibility to have an application process and the review process for programs that are currently eligible and programs that may become eligible.

A member asked who has responsibility for a released organ, and the staff answered that the responsibility stays with the host OPO where the donor originated.

A member asked how many facilitated pancreas programs there are. Staff and the Chair answered that there are about 44 facilitated pancreas programs, but 6 pancreata were actually transplanted from a facilitated pancreas offer last year. Members discussed possible reasons for this discrepancy, such as difficulties with timing and the bypass system not bypassing provisional yes. A member expressed frustration with provisional yes, because many centers say they are interested without intention to take the organ or do not move forward with the offer due to changes in organ status during recovery. Provisional yes is also difficult because centers have the right to request additional testing or visualization before truly accepting. Members also discussed a potential problem in the system is that once the pancreas moves to facilitated pancreas, centers that entered a provisional yes are negated if they are not a facilitated pancreas center. Trends in facilitated pancreas offers also depend on OPO behavior, such as if centers exhaust their match run or accrue a certain number of provisional yes responses and then pause.

Members discussed difficulty with provisional yes and timing of admitting candidates, arranging transportation, and getting a surgical team ready when they are far down the list. Staff explained that the OPTN Operations and Safety Committee has discussed this, and suggested a tiered approach to offers that ultimately was not supported by public comment.

Next steps:

The Committee will revisit discussion on facilitated pancreas at a future meeting. Staff will investigate getting a demo set up for the Committee to show how facilitated pancreas offers work.

Review Boards Workgroup

A member of the Review Boards Workgroup presented an update to the Committee.

Presentation summary:

The presenter outlined the Workgroup purpose and scope, noting that the Workgroup will work to develop review board recommendations for the Kidney and Pancreas Committees by January to discuss.

The Workgroup has already reached a decision on some attributes. For kidney, DR matching, blood type, and proximity efficiency are ineligible for exception requests. Medical urgency, longevity (Estimated Post-Transplant Survival), pediatrics, kidney after liver (KAL) safety net, waiting time, and prior living donor are kidney attributes identified as eligible for exception requests. For pancreas, blood type, CPRA, proximity efficiency, and organ registration are ineligible for exception requests. Prior living donor, pediatrics, and waiting time are pancreas attributes the Workgroup identified as eligible for exception requests. The Workgroup is still considering CPRA for both kidney and pancreas, as well as pancreas medical urgency.

The Workgroup will next review how review boards operate in lung, work to specifically define criteria within each attribute considered for exception requests and check in with the OPTN Data Advisory Committee.

Summary of discussion:

The chair asked if current policy says anything regarding primary non-function after simultaneous heart-kidney, lung-kidney, or kidney-pancreas. A member answered that in their experience with a patient after non-function, qualifying time was returned to the patient. Another member responded, adding that patients with primary non-function may be given wait time back, but are not considered part of the safety net anymore. The presenter clarified that the Workgroup is looking into this.

A member asked if the Workgroup had defined candidates who fall just outside the KAL safety net timeline any further, and the presenter responded that the Workgroup is not currently making policy, just recommending what attributes should be considered in a review board framework. A staff member clarified that liver has standard exceptions and the review board process to handle cases that fall outside these standard exceptions.

The Vice Chair asked if the OPTN Ethics Committee is advising the Workgroup regarding prior living donor outside the United States, and the presenter responded that the Workgroup will investigate that moving forward. A member added that a needs assessment would be helpful in determining what percentage of the population this situation describes. The presenter explained that the Workgroup is primarily concept-driven at the moment, but will look into data regarding this as the discussion progresses. A member asked if the priority would extend to non-US nationals as well, and the presenter stated that they would take this back to the Workgroup. Staff cautioned members that the Workgroup is having very preliminary discussions and that the Workgroup will investigate the feasibility of giving priority to prior living donors who donated outside the US further considering current policy.

OPTN Ad-Hoc Multi-Organ Transplantation (MOT) Committee

The Vice Chair, a member of the MOT Committee, gave an update to members about the MOT Committee's progress.

Presentation summary:

The Vice Chair explained the MOT Committee charge to develop and propose policies that address multiple organ groups and address multiple organ allocation and explained progress to date, including developing the proposal to establish eligibility criteria and the safety net for heart-kidney and lung-kidney allocation. The proposal was approved by the Board in June 2022 and is pending implementation.

The MOT Committee's timeline was shown, and the presenter explained that the MOT Committee would be providing input to the Kidney and Pancreas Committees for continuous distribution of KP. Current MOT Committee work includes ongoing support to the continuous distribution projects and evidence gathering for simultaneous liver-kidney (SLK) allocation and identifying priority shares in kidney multi-organ policies. The SLK project is aimed at aligning SLK policy with heart-kidney policy and is slated to go out for the January 2023 public comment period. The priority shares in kidney multi-organ policies is aimed at updating the framework for kidney multi-organ allocation and is tentatively slated to go out for a concept paper for January 2023 and a proposal for August 2023.

Summary of discussion:

A member asked if the MOT Committee discussed allocation to both the kidney list and MOT candidates if there are multiple kidneys offered. The Vice Chair answered that the MOT is discussing this, but that the Committee is in the data gathering stage still. The Chair asked about estimated implementation of the heart-kidney and lung-kidney safety and if the policy aligns with liver-kidney. Staff answered that the projected implementation timeline is mid-2023. The Vice Chair responded that the policies align with liver-kidney, especially in trying to keep the safety net at one year.

There were no additional questions or discussion. The meeting was adjourned.

Upcoming Meetings

- November 7, 2022 (Teleconference)

Attendance

- **Committee Members**
  - Rachel Forbes
  - Oyedolamu Olaitan
  - Antonio Di Carlo
  - Colleen Jay
  - Dean Kim
  - Diane Cibrik
  - Jessica Yokubeak
  - Randeep Kashyap
  - Katherine Cyran
  - William Asch
  - Mallory Boomsma
  - Maria Friday
  - Muhammad Yaqub
  - Nicolae Leca
  - Nikole Neidlinger
  - Ty Dunn
  - Rupi Sodhi
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Raja Kandaswamy
  - Josh Pyke
- **UNOS Staff**
  - Joann White
  - Kieran McMahon
  - Carol Covington
  - James Alcorn
  - Kaitlin Swanner
  - Lauren Mauk
  - Lauren Motley
  - Sarah Booker
  - Kayla Temple
  - Krissy Laurie
  - Lindsay Larkin
  - Sara Moriarty
  - Shelby Jones
  - Terry Cullen
- **Additional Guests**
  - Elijah Pivo (MIT staff)
  - Nikos Trichakis (MIT Staff)