

OPTN Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup

Meeting Summary

June 17, 2022

Conference Call

Rachel Forbes, MD, Chair
Oyedolamu Olaitan, MD, Vice Chair
Martha Pavlakis, MD, Chair
Jim Kim, MD, Vice Chair

Introduction

The Kidney & Pancreas Transplantation Committee Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 06/17/2022 to discuss the following agenda items:

1. Project Timeline
2. Allocation Components Outside of Composite Allocation Score (CAS): Released Organs
3. Allocation Components Outside of Composite Allocation Score (CAS): Introduction to Review Boards

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

1. Project Timeline

The Workgroup discussed the project timeline and the upcoming milestones.

Presentation summary:

The Workgroup has several upcoming milestones:

- Finalize decisions on operational components
- Release update paper for August 2022 public comment
- Regional meeting and stakeholder committee presentations
- Review Scientific Registry of Transplant Recipients (SRTR) Kidney-Pancreas Simulated Allocation Model (KPSAM) modeling results
- Adjust draft framework as needed
- Submit second modeling request and review results
- Finalize new framework
- Policy drafting
- Develop proposals and achieve Committee vote to send to public comment
- Release proposals for public comment
- Review Public Comment feedback, discuss any post-public comment changes, and Committee vote to send to the OPTN Board
- Submit proposals to the OPTN Board for approval

Due to the extensive discussions the Workgroup may have ahead, the leadership of the Kidney and Pancreas Committees recommend extending the project timeline, with a new target date for proposals to go to the Board in December of 2023, and out to public comment in August of 2023. This will allow time for the Workgroup and Committees to:

- Review results from the KPSAM modeling requests
- Provide updates to the community on the modeling and analysis phase of the project
- Review public comment feedback, with a concept paper released for the August 2022 public comment cycle
- Make adjustments to framework as needed and develop the second modeling request

Summary of discussion:

One of the Chairs shared that the goal is to take as much time as is necessary to build the kidney and pancreas continuous distribution allocation frameworks, no more and no less. The Chair noted that the Workgroup is somewhat constrained by the public comment cycle timeline. The Chair shared that the Committees' leadership felt that rushing the project would be harmful, and that it is important to ensure the allocation framework is fully vetted among the Workgroup and the Kidney and Pancreas Committees. One member agreed, adding that this project is too important to rush through. The member noted that it would be worthwhile to ensure the Workgroup has ample time to review and analyze KPSAM modeling, respond with modifications and recommendations, and then release a fully vetted allocation framework for public comment.

Another Chair agreed, and expressed support for a second round of public comment. The Chair continued, noting that it will be important to ensure the community understands and is aware of the results of the modeling. The Chair remarked that all Workgroup, Kidney Committee, and Pancreas Committee members have a responsibility to update colleagues and transplant peers at different programs and Organ Procurement Organizations (OPOs). Another Chair agreed, adding that it is helpful to pull together a few slides or materials to update their own transplant center. The Chair continued, explaining that they get their program together – surgeons, nurses, coordinators, doctors, research folks, etc. and update them on the status of the project. The Chair added that those slides or materials can then be shared with OPO colleagues, so the community can remain engaged and so serious and valid objections and considerations can be discussed at the appropriate stages. The other Chair agreed, and wondered if it would make sense to have Committee members give individualized presentations to different OPTN member types, so that the community understands what's being modeled and discussed, and share any concerns. The Chair noted that this would need to be a small group, so that community members are comfortable speaking up. The other Chair responded that this doesn't need to be an official project, but could be more casual and unofficial sharing of slides amongst community members in order to ensure the information is shared and understood within the community.

The Workgroup achieved unanimous support for an alternate, extended timeline for the Continuous Distribution of Kidneys and Pancreata projects, such that the projects would be released for the August 2023 public comment cycle.

2. Allocation Components Outside of Composite Allocation Score (CAS): Released Organs

The Workgroup reviewed current released organs policy for kidneys, kidney-pancreas (KP), pancreas, and pancreas islets.

Presentation summary:

OPTN Policy 8.8: Allocation of Released Kidneys states that the host OPO may continue allocation according to the original match run; allocate the kidney using a released kidney match run, or contact the OPTN for assistance allocating the kidney.

OPTN Policy 11.8: Allocation of Released Kidney-Pancreas, Pancreas, or Islets allows the host OPO to continue allocation according to the original match run; contact the OPTN for assistance allocating the organ; or allocate the kidney-pancreas, pancreas, or islets to a potential transplant recipient (PTR) at the

transplant program that originally accepted the organ(s). If allocating to a pancreas-alone PTR at the same program, the kidney must be allocated according to *Policy 8.8: Allocation of Released Kidneys*.

The OPO Committee provided feedback at their latest meeting:

- Current policy creates more cold time; there is no time requirement for transplant programs declining the offer and releasing it back to the OPO to reallocate
- Local back up should remain an option at OPO discretion
- Maximization of medically complex kidneys is most important in these scenarios

Considerations for continuous distribution:

- Use location of where organ is when released
- Increase the weight of placement efficiency to make local offers more likely

Questions for discussion:

1. Is this a policy that can be standardized across organs, or are there clinical differences which require different operational policies?
2. These organs can safely be classified as hard to place since they are released. Is this an opportunity to increase the weight or importance of placement efficiency/utility in order to decrease the changes of a discard?
3. When calculating distance, should we use the actual location of the organ or the original donor hospital?

Summary of discussion:

One Chair remarked that released organs will be difficult to standardize across organ types, particularly as kidney and pancreas have key clinical differences. The Chair noted that the quality of the kidney plays a role in released allocation as well. Another Chair agreed, emphasizing clinical differences between organs.

A Chair commented that once a surgeon has seen the organ, they will know if a kidney is one they will use for anyone else listed at their program. The Chair noted that if the KP is released for a recipient issue, a surgeon may have already organized a back-up candidate to accept that KP. Having a back-up candidate at the center where the pancreas is released increases the chance that organ is utilized. The Chair remarked that this is likely also true for a kidney. The Chair continued, noting that, if the intended recipient can't utilize the organ, the next question should be whether the surgeon would utilize the same organ for another candidate. If the surgeon doesn't have any other candidate at the center appropriate to receive the organ, the Chair continued, then the kidney should be allocated to a nearby center to minimize cold time and utilize the organ. The Chair remarked that the kidney should only be released and allocated from the original donor hospital if it's a young and healthy organ declined for a recipient issue. The Chair noted that this would be a very small minority of cases, as there will be increased logistic and costs with shipping a kidney back to the host OPO as opposed to keeping it local. The Chair added that there is a downside, where programs may import KPs, choose not to utilize the pancreas, and place the kidney with one of their kidney candidates.

Another Chair agreed that released organs policy shouldn't be standardized across organs, and shared that the Kidney and Pancreas Committees discussed this previously in the development of the circles-based distribution. The Chair commented that, regardless of the reason an organ is declined once it reaches the accepting center, it should not be assumed that only medically complex kidneys are released. The Chair continued that, across the board, allocation of released kidneys should try to be local to where the kidney physically is, to reduce cold time. The Chair noted that utilizing the original

match with the donor hospital at the center doesn't make much sense, even if it's a young donor. The Chair added that minimizing cold time and keeping the organ local to its released location would maximize usage.

One member remarked that, though continuous distribution was intended to be more equitable, keeping a released organ close to the previously accepting center would be helpful to improving utility. The member recommended including monitoring to ensure the policy isn't abused. A Chair responded that the kidney shouldn't necessarily stay at the previously accepting center, but that this could depend on the timing of reallocation and cold time of the organ. The Chair wondered if there was any data available since the new policy was implemented on where organs traveled and what utilization rates were to help base some of these decisions on. The Chair added that the previously accepted center shouldn't necessarily get center back-up because it creates the opportunity for centers to game the system. A member responded that monitoring would be helpful with that consideration. The member added that organs are traveling a greater distance, and because offer decisions are delayed somewhere in the centers' processes, organs generally arrive at the accepting center with greater cold time.

3. Allocation Components Outside of Composite Allocation Score (CAS): Introduction to Review Boards

The Workgroup received an introduction to and overview of review boards, their operations, responsibilities, and processes, and their role in a continuous distribution framework.

Presentation summary:

Informational sessions will be done for the Workgroup to review or learn about a system or operational behavior in preparation for future discussions and decision making as we move through continuous distribution.

The Organ Center Operations Coordinators perform waitlist maintenance, manage vascular composite allografts (VCA) operations, review board case processing and operations, and kidney paired donation. The Organ Center Operations' team's role in review board case processing is to submit, monitor and notify centers of case outcomes, as well as to act as a resource for programs and review board participants.

The Kidney waitlist is currently managed within three current statuses – active, medically urgent, and inactive – and specific adult and pediatric waiting time rules. Adult waiting time is based on dialysis date, or earliest date on or after registration with qualify glomerular filtration rate (GFR) or creatinine clearance (CrCl). All kidney candidates accrue waiting time while inactive.

The Pancreas, KP, and Pancreas Islets waitlist is managed within two current statuses – active and inactive – and organ-specific and age-specific waiting time rules. Pancreas, Pancreas Islet, and pediatric candidates qualify for waiting time once they are registered on the waitlist. KP candidates must also qualify for kidney waiting time, and be on insulin to qualify to accrue waiting time. All Pancreas, KP, and Pancreas Islet candidates accrue waiting time while inactive. Pancreas Islet candidates retain waiting time through three registrations.

Operational guidelines and OPTN policy outline processes and timelines for review boards. Exceptions are utilized when a candidate does not meet the criteria listed in policy, but the program feels that they are as medically urgent as someone who does. Review board members quickly review specific exception requests for candidates on the waiting list, and collectively determine via vote whether the candidate's listing and status is appropriate, based on clinical information in compliance with OPTN policies. A full list of review board responsibilities can be found in their respective guidelines.

The Exception Process:

1. A transplant program submits an exception for their candidate, including the justification narrative supporting their request
2. Organ Center Operations staff reviews the request, redacts any personally identifiable information, and submits to the review board
3. An odd number of review board participants are assigned to each exception. If they do not vote within three days, they will be replaced by a random review board participant. If a review board participant is not able to vote, they may request that the case be reassigned to another randomly selected reviewer. Review board participants can also mark themselves as out of office to prevent case assignments.
 - a. The system sends emails to participants when the case is assigned, to remind the review board participant on the second day, and to alert a review board participant that the case has been reassigned due to lack of voting
4. An exception case will close when the majority approval or denial is met, or the case reaches the end of the timeline for voting of five days, whichever is first. The transplant program will receive an email notification with the outcome of the exception.
 - a. Votes are tallied utilizing the Robert's Rules of Order definition of a majority (simply more than half) to determine the case outcome of approved or denied
 - b. In the event of a tie, benefit should be given to the patient and the exception will be assigned
5. If the exception request was denied, the transplant program has the option to submit an appeal within three days of the denial notification. Once submitted, the five day clock starts on the case's lifespan.
 - a. The first appeal is reviewed by the participants that denied the initial request; the second appeal goes to a reviewing body

Summary of discussion:

One member shared that they have experience on the regional and national liver review boards, and asked if there would be a separate review board for pediatric patients. Staff explained that the Committees will need to discuss and determine that. The Committees could choose to assign specific pediatric reviewers to pediatric cases, or create a separate board so pediatric doctors are always assigned to pediatric cases. The member noted that it is an important consideration, and shared that in their experience, the review board would automatically approve on the sole basis of the patient being pediatric, or else recommend workups or treatments that weren't appropriate for pediatric patients. The member added that there is value to having pediatric experts weigh in and have a designated role.

A Chair expressed support for a review board, and recommended including members who have experience with liver review boards in the first few review boards convened, so there is some historic perspective. A member responded that review board participation is a great experience, and that members should consider serving in that role if possible. A Chair thanked the member, noting that reviewers will be needed further down the line.

One of the Chairs pointed out that the current Kidney Medical Urgency policy includes a retrospective review, and asked if the review board would review prospectively. Staff explained that the Committee has the option to determine between retrospective and prospective review. Staff noted that the review board implemented for Continuous Distribution of Lungs is all retrospective, but that the Kidney and Pancreas Committees could consider prospective review.

One member asked if there was an anticipated volume for review board cases. Staff responded that there is not an anticipated volume, as the allocation system will be completely new in continuous distribution. Staff added that there isn't any current review board to compare with for Kidney or Pancreas.

Upcoming Meetings

- July 8, 2022 (Teleconference)

Attendance

- **Workgroup Members**
 - Rachel Forbes
 - Silke Niederhaus
 - Martha Pavlakis
 - Jim Kim
 - Abigail Martin
 - Arpita Basu
 - Bea Concepcion
 - Cathi Murphey
 - Peter Kennealey
 - Tarek Alhamad
 - Todd Pesavento
 - Caitlin Shearer
- **HRSA Representatives**
 - Bryn Thompson
 - Jim Bowman
- **SRTR Representatives**
 - Ajay Israni
 - Jon Miller
 - Peter Stock
- **UNOS Staff**
 - Joann White
 - Rebecca Brookman
 - Kayla Temple
 - Lauren Mauk
 - Lauren Motley
 - Matt Cafarella
 - Darby Harris
 - Kaitlin Swanner
 - James Alcorn
 - Jennifer Musick
 - Alison Wilhelm
 - Stryker Ann Vosteen