

**OPTN/UNOS Kidney Committee  
Meeting Minutes  
September 24, 2018  
Conference Call**

**Nicole Turgeon, MD, FACS, Chair  
Vincent Casingal, MD, Vice Chair**

**Introduction**

The Kidney Committee met via teleconference on 09/24/2018 to discuss the following agenda items:

1. Welcome and Announcements
2. Geography Frameworks Presentation
3. Dual and En Bloc Implantation Recommendations
4. Pancreas Program Functional Inactivity Public Comment

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

**1. Welcome and Announcements**

Attendees were welcomed to the conference call and the agenda was reviewed. Committee members should make travel arrangements for the in-person meeting on 10/15/2018.

**2. Geography Frameworks Presentation**

Data summary:

The Ad Hoc Geography Committee identified three distribution frameworks that are consistent with the OPTN Final Rule, and is currently seeking community feedback within public comment to identify a single preferred distribution framework to be used across all organs. In the meantime, organ-specific committees are developing their preferred frameworks. The Kidney-Pancreas Work Group removed DSA and region from organ allocation policies and got their SRTR modeling request in on 09/04/2018.

The three distribution frameworks are:

- Fixed distance from donor hospital (concentric circles). This is the implementation of one more fixed distance circles centered around the donor hospital. Candidates in first circle would receive organ offers before second circle. Advantages are that it is easy to explain and that it extends the distribution area particularly for medically urgent patients. Disadvantages are that there are fixed boundaries, so it is possible that someone 5 nm outside the circle that has a much higher medical urgency would not receive an offer. Also, differences in population density may affect patients with similar matching characteristics.
- Mathematical optimization (districts and neighborhoods). This framework could take fixed distance into account to create a limited number of large districts or a large number of localized neighborhoods. Advantages are it would provide more consistent results and can be monitored or scaled based on population densities across the country. Disadvantages are boundaries could be complex and not uniform, as well as the similar issue of fixed boundaries problems similar to the fixed distance framework.
- Continuous distribution (borderless). This framework would reward points for proximity and take in other characteristics such as medical urgency or candidate match.

Advantages are that two patients with similar suitability would be treated much the same way, priority would consider specific clinical characteristics about the candidate, and it is more likely that an organ offer would be matched efficiently with candidates with the highest medical need, receiving points for medical need, match, and proximity.

Disadvantages are it may not produce concentrated matches and may be difficult to understand.

The KP Work Group is currently two modeling frameworks with the SRTR. No final decisions have been made until modeling can be considered, which will take approximately 10 weeks. Modeling results will be available around mid-November. The frameworks being modeled are fixed concentric circles and a hybrid between fixed concentric circles and continuous distribution model.

There are two different-sized concentric circle frameworks being modeled, 150 nm/300 nm and 250 nm/500 nm. Feedback has been implemented based on meetings with the Geography Committee. These meet the Principles of Distribution and are justifiable based on available travel and outcomes data.

The hybrid model consists of a fixed concentric circle at 500 nm with awarded proximity points for candidates inside or outside of the circle. A shallow/shallow linear variation awards 1 point to candidates closest to the donor hospital within the 500 nm concentric circle and 0 points at the 500 mile limit. Outside of the 500 nm circle, 2 points close to the edge and 0 points when out to 2500 nm. A steep/steep linear variation values proximity more so than the shallow variation, so a candidate closest to donor hospital would receive 2 proximity points and 0 points at the limit. Candidates outside of 500 nm circle close to the edge would receive 4 points and at 2500 nm would receive 0 points.

There are three separate models:

- Model 1 consists of a single fixed 500 nm concentric circle with no proximity points. Kidneys are allocated based on the current kidney allocation system (KAS).
- Model 2 is the shallow proximity model with a 500 nm circle with 1 point awarded on a linear relationship based on the proximity of the candidate to the donor hospital. The same applies for the national distribution outside of 500 nm circle except closest donors closest to the edge of the circle start with 2 points with a linear relationship down to a candidate 2500 nm receiving 0 points (KAS classification is based on medical urgency, but no additional points for proximity).
- Model 3 is the steep proximity model essentially the same as above, but favors proximity more than the shallow model so candidates closest to donor hospital within 500 nm circle receive 2 points and 0 at 500 nm range. Then outside the circle, the closest candidate to 500 nm circle receives 4 points with a linear relationship down to candidates at 2500 nm receiving 0 proximity points. Again, kidneys allocated based on current KAS classification.

A brief overview was given of several metrics for the SRTR modeling and potential stratifications and considerations for SRTR modeling with the metrics. These will be available on SharePoint to be individually reviewed by Kidney Committee members in more detail following the call.

#### Summary of discussion:

One question was regarding how the geographically isolated areas (Hawaii, Puerto Rico, Alaska) would be dealt with in the fixed distance framework. This issue is currently being considered by the Geography Committee while modeling is being conducted.

One question was regarding how the Work Group came up with the circle sizes. Through discussion on the last call, they felt there was a point where it doesn't matter what point you get for distance, so the circle sizes came from consensus of the group. The sizes can still be adjusted and are more for modeling purposes at this point.

Next steps:

Further questions can be emailed to the UNOS liaison.

### **3. Dual and En Bloc Implantation Recommendations**

Data summary:

The project start is planned for Q4 of 2018 with programming starting in November. Rollout will be Q3 of 2019. The timeline is subject to change.

The first phase of the project will be release 1 waitlist changes when centers will be allowed to opt in/opt out to receive dual and en bloc offers. There will be a month in between release 1 and 2 to give centers time to opt in. The second phase will be release 2, which will include DonorNet changes to include the new classification, as well as a new en bloc match run.

Dual and en bloc kidney acceptance criteria policy language is 5.3.G, which will be available for Kidney Committee members to review in more detail. The new acceptance criteria in phase 1 will have new questions added to the kidney and KP candidate record to accept dual kidneys and en bloc offers, new defaults that can be set for new candidates, and the ability to update existing waitlist.

For new KI candidates there will be listing defaults that can be set up with ranges for single or dual and whether or not dual or en bloc for kidney can be accepted. For existing KI candidates, the waitlist can be updated for dual and en bloc local or imports.

Allocation of dual kidneys policy language is 8.6.A available to members for detailed review. The DonorNet kidney match run changes will include sequence D (KDPI  $\geq 35$   $\leq 85\%$ ) new classifications and sequence C (KDPI  $>85\%$ ) new dual kidney listings. By adding dual kidneys into the existing classification, it creates the potential for a candidate to appear twice on the list, once for single and once or dual. This will be addressed by having display message come up that there's a dual kidney offer.

Allocation of en bloc kidneys is 8.6.B available to members for detailed review. A new en bloc match run list will be created, basically a copy of sequence A. Donor weight will be less than 18 kg, where en bloc match run will be automatically generated. If donor weight is over 18 kg and the OPO chooses to run an en bloc kidney match run, they can do so. The candidate's KDPI donor acceptance criteria will not be used during en bloc match run screening and will not display on kidney en bloc match run initiation screen. For matches, a message will indicate it is an en bloc kidney run. All the language is subject to change.

If there is a need to split the en bloc or dual kidneys, the policy 8.6.C mandates that it must be documented and the organs be released according to policy 5.9. For split en bloc kidneys, they must be allocated with a single match run, so would go to anyone using KDPI. The DonorNet kidney match run list change is that the OPO will run the second kidney match for a donor display new field to confirm allocation of the second kidney. The waitlist change is that there are new fields to capture a reason for the split on the kidney candidate removal screen. Going back into the split kidney match run, the system would recognize it was already an en bloc match and give the option to allocate the remaining kidney from a separated en bloc kidney offer.

The solution proposed does not necessarily go along with the intent of what the policy changes were supposed to do. When the policy was being developed, the Committee tried to make sure it

did not disadvantage any populations of patients. When saying the second kidney would be allocated along a match run, it was to prevent centers from keeping the second kidney and not giving other patients on match runs opportunities for the kidneys. They didn't take into account the efficiency of the system and what was happening with the first kidney, which is that once it is allocated en bloc and they decide to split, the KDPI is masked for the first kidney. To run a second match run with a KDPI with the same kidney seems inefficient.

The solution was a suggestion from the Board of Directors that was discussed at previous meetings. Since everybody is opting in for the en bloc kidneys for their patients, those are typically the same patients that will use small single kidneys. Since the KDPI is masked for the first kidney, the same match run should be used, calling it an en bloc/small single match run.

#### Summary of discussion:

One concern was that with all the changes mentioned on the call so far, they would seem to add to the cold ischemia time, and that needs to be considered.

One comment about KDPI is once the kidneys are split, the KDPI masked is the KDPI of the single kidney. However, it will not be on the initial match run for the en bloc, so the people accessing it for the small single will not see it. It doesn't make sense to mask it for one and not the other. Another reason for this is they will currently allocate the en blocs in sequence A and a lot of pediatric programs would be excited to have access to small single kidneys that they did not have before because KDPIs were in the 60s, 70s and 80s. This will need to be made clear during education of the process.

Another comment was that when splitting the kidney, it is usually an adjustment that is made right on the spot, so will the adjustment transfer to the surgeon accepting the other kidney? The surgeon of the second kidney will have a choice to make, which is part of the downstream effect.

#### Next steps:

Any questions can be emailed to UNOS IT staff.

### **4. Pancreas Program Functional Inactivity Public Comment**

#### Data summary:

The primary goal for the functionally inactive pancreas transplant programs project is to improve waitlisted patient and transplant recipient outcomes. The proposed changes will create new thresholds for identifying functionally-inactive programs that operate below the level adequate for waitlisted candidates, as well as improve patient access to relative information regarding wait time and options for other pancreas programs in their areas and may improve outcomes and access. Other goals include promoting efficient management of OPTN by reducing review of pancreas programs by MPSC and promotes transplant recipient safety.

Historically, functionally inactive was defined as 1 pancreas transplant in 6 consecutive months. Reviewing inactive programs is an administrative burden on the MPSC. The definition is too broad in reviewing all low volume programs (even with shorter waiting times), causing 44% of all programs to be reviewed from 2011 to 2016. The definition is also too inflexible in reviewing small volume programs transplanting with a short wait time.

Additionally, patients need better communication about program needs and transplant options. While patient safety is the impetus for the reviews, 67% of patients listed at a program while it is under functional inactivity review are not getting listed at another program.

There is some evidence that lower pancreas graft survival occurs for KP recipients being at a small volume center, highlighting the need to review certain small volume centers for functional inactivity because of potential impact on outcomes.

The proposed changes are:

- The definition of functional inactivity will be modified to require both criteria of fewer than 2 transplants in 12 consecutive months and have an average waiting time above the national average or have no waiting time at all because no one is listed. The recommendation will be that only small volume programs with longer waiting times be reviewed.
- Functionally inactive programs will be required to notify their patients, letting them know of geographically proximate pancreas programs, as well as their average waiting time compared to the national average or having no waiting time. Patients in small volume programs wait average 9.8 months longer than larger volume programs.

Under the changes, pancreas programs will be reviewed for functional inactivity if they meet the new definition of functionally inactive. If a program is flagged, they will send out the letter with the inflation of the proximate programs within 125 miles or in-state, along with those programs' waiting times compared to national average.

For OPTN to implement the proposal, they will create a report for programs to identify the average wait time compared to national average. This would be implemented in communication policies in Transplant Pro.

The Pancreas Committee will request data (number of pancreas programs under review, number of programs inactivated while under functional activity review, trends in relisted candidates, patient and graft survival pancreas recipients stratified by center volume) to assess the proposed policy pre and post implementation. The Committee also discussed compiling a best practices document to help small programs grow to get the required 2 transplants a year.

Community members are asked to comment on whether similar proposal changes should be considered for other organ types such as heart, lung, liver, and kidney. The feedback will be given to the MPSC to consider if a change should be made to functionally inactive programs of other organ types

#### Summary of discussion:

One question was on the incorporation of the national average wait time into determining whether a pancreas program becomes functionally inactive. Pancreas transplant is different in that time waiting for a pancreas does not necessarily increase morbidity and mortality the way it does for kidney. An example was given that a type 1 diabetic with GFR of 19 would be listed for KP and made inactive while being worked up for potential live donors for kidney alone. Then maybe 2 years later needs the kidney transplant, so will not be reactivated for pancreas until 6 months after the kidney transplant. This could be 2 to 2-1/2 years of inactivity that does not reflect any inefficiencies of the program. This issue has come up in some regional meetings where they feel it should only apply to active patients, and it will be discussed at the next in-person Pancreas Committee meeting. Highly sensitized will also have a longer wait time.

#### **Upcoming Meetings**

- October 15, 2018, in-person meeting in Chicago, IL

## Attendance

- **(Sub)Committee Members**
  - First Name Last Name
  - First Name Last Name
- **HRSA Representatives**
  - First Name Last Name
- **SRTR Staff**
  - First Name Last Name
- **OPTN/UNOS Staff**
  - First Name Last Name
- **Other Attendees**
  - First Name Last Name