OPTN/UNOS Kidney Committee
Meeting Minutes
June 12, 2017
Conference Call

Mark Aeder, MD, Chair
Nicole Turgeon, MD, FACS, Vice Chair

Introduction

The Kidney Committee met via Citrix GoTo Training teleconference on 06/12/2017 to discuss the following agenda items:

1. Improving Dual Kidney Allocation Project
2. Improving En Bloc Kidney Allocation Project

The following is a summary of the advisory group's discussions.

1. Improving Dual Kidney Allocation Project

Summary of discussion:

Continued efforts are being made to ensure that the Dual Kidney Allocation project reaches public comment by the end of July. A draft policy involving the Kidney Donor Profile Index (KDPI) is being further discussed and revised in order to move forward. In particular, focus is placed on Sequence C with KDPI ranging from 35 to 84 percent and Sequence D with KDPI greater than or equal to 85 percent.

Revisions to the draft policy include adhering to only one match run for the dual allocation, especially with high KDPI kidneys. For example, original offer for high KDPI involves selecting whether one wants the kidney as a single or as a dual. If one selects the kidney as a single, it will then not be offered as a dual. If dual is desired, it is possible to opt in early in the process. This revision will fix problems that arise in Sequence D. In addition, a Sequence D hierarchy of offers will move from highly sensitized to zero ABDR mismatch, the local safety net, local, local (dual opt-in), regional, regional (dual opt-in), national, and finally national (dual opt-in). If the final national run yields no acceptance, it will be possible for those earlier in the match run to denote if they would like to be informed of a situation in which the kidneys can be offered as dual. Sequence D now includes dual opt-in candidates in classifications 31, 33, and 36 in *Policy 8.5.K*. For Sequence C, local, regional, and national dual opt-in options were added to the end of the match run priority list. Sequence C now includes classifications 48 through 50 as dual opt-in in *Policy 8.5.J*, which continues to allow the possibility of rare Sequence C dual kidney allocations. New policy language is also added to 8.6.B to synthesize changes made in *Policy 8.5.J* and *Policy 8.5.K* for double kidney allocation while also referencing adherence to *Policy 5.9* on released organs. Overall, these changes are meant to expedite and streamline the placement of kidneys.

A vote was taken concerning the revisions made for public comment to the Improving Dual Kidney Allocation project. All present voting members were unanimously in favor of the revisions prepared for public comment. No votes were lodged against the project as well as no abstention.

2. Improving En Bloc Kidney Allocation Project

Summary of discussion:

As an update, the Board of Directors met on June 6, 2017 and declined to approve this proposal. 16 Board members voted in favor, 21 Board members voted against, and there was zero abstentions. In particular, Board members voiced two major concerns:

- There was apprehension about reliance on the current *Policy 5.9: Released Organs* for ways in which to allocate kidneys that are designate en bloc but later split.
- There was discussion that the weight threshold for en bloc kidneys should be lower.

The Kidney Committee will now focus on clarifying and rectifying misconceptions concerning these two areas. For example, the concern over *Policy 5.9* involved knowing if the split kidney would remain at the center that performed the split and if the current policy would delay the allocation of the split of the split kidney. A data review has shown, however, that most cases involve the kidney remain in local backup. As such, over 90 percent of these kidneys stay at the center from which they originated. This information clarifies some of this concern over *Policy 5.9* and should be highlighted moving forward. Moreover, it is important to note that kidneys allocated en bloc and subsequently split are rare at approximately 50 donors per year. With data revealing that over 90 percent remain at one institution, this reflects a very small number of situations where a scenario plays out with a split kidney leaving the institution that performed the split. With regard to the weight threshold, the committee must discuss lower threshold options for presenting to the Board of Directors. The Improving Kidney En Bloc Allocation project will now go out for a second round of public comment in which it will be realigned with the Improving Dual Kidney Allocation project. The deadline for this second round of public comment is very tight.

Further delving into the discussion points arising from the Board of Directors meeting on June 6, 2017, clarification must be made available on the fact that *Policy 5.9* does allow for local back-up. *Policy 5.9* is the status quo, and it also encompasses the most fair, transparent option available. Equity and transparency are essential factors for consideration, and this policy is vital to ensuring continued efforts in both arenas. Prescriptive language is being avoided and is generally unnecessary following talks with United Network for Organ Sharing (UNOS) legal counsel. While some voiced concerns about releasing the second split kidney, equity and transparency are guided by *Policy 5.9.* It is important to note that, under current policy, splitting and keeping the second kidney is a substantial violation of policy. Typically, a local backup run does allow the center to keep the second kidney. As such, centers are currently functioning under the proposed rules; it just is not perceived that way by the centers. As such, it is imperative that this be further explained and clarified to the Board of Directors moving forward. Appropriate metrics for monitoring the amount of en bloc kidneys that are split, as well as number of discards of en blocs or the split second kidney, will further provide relevant data and ensure that avenues for further changes are open.

Relevant data were utilized to develop weight thresholds. This data included donor weight and kidney disposition between the years 2010 and 2015. This data provided information on exactly where en bloc and singles began to intersect. This intersection tended to occur at approximately 18 kilograms. Additionally, data on the percent of transplants en bloc versus single by Organ Procurement and Transplantation Network (OPTN) region and donor weight yields telling information. Between 16 and 18 kilograms, many regions still perform en bloc, yet there is notable fluctuation between regions. For example, regions 3, 6, and 7 do a considerable amount of en bloc at this weight range while regions 2, 5, and 9 do a large amount of singles.

Given this, it is important to clarify that options are still available to proceed as an institution deems fit. Data between 19 and 20 kilograms reveals that all the regions perform a majority of singles at this donor weight range.

Given the discussions arising from the Board, votes were taken on changing the weight threshold to 18 kilograms, as well as sending the En Bloc Allocation proposal out for a second round of public comment. Before voting, a discussion took place asking if any members would recommend carving out an exception within *Policy 5.9* for en bloc kidneys and the release of the second split kidney. No committee member wanted to carve out an exception in the status quo policy, but some agreed that some further data collection and educational outreach should take place around *Policy 5.9* moving forward in order to make the Board more aware of the process. The first vote, all voting members unanimously approved lowering the mandatory en bloc allocation donor weight threshold to 18 kilograms. The second vote saw all voting members unanimously approving sending the En Bloc Allocation policy out for a second round of public comment.

Next steps:

The timeline for En Bloc Allocation has been updated given that the Board of Directors did not approve it on June 6, 2017. Following the approved committee vote to move forward with a second round of public comment, the Kidney Committee will need to reconvene between June 13 and July 6, 2017 to vote on any changes made to the proposal. The proposal due date is July 7, 2017. Public comment will take place between July 31 and October 2, 2017 with a final briefing paper due on November 10, 2017 before a Board of Directors vote no later than December 5, 2017.

Regional representatives are asked to let UNOS know as soon as possible if they are unable to attend their upcoming regional meetings. If they are unable to attend, a backup presenter must be identified. These meetings are being held at various times between August 18 and October 2, 2017.

Upcoming Meetings

- July 10, 2017 at 5pm EST/2pm PST
- August 14, 2017 at 12pm EST/9am PST

Attendance

- **Kidney Committee Members**
    - Mark Aeder, Chair
    - Nicole Turgeon, Vice Chair
    - Eileen Brewer
    - Vincent Casingal
    - Ajay Israni
    - Colleen Jay
    - Monica Johnson
    - Rob Linderer
    - Martha Pavlakis
    - Fuad Shihab
    - Andrew Weiss
    - Mark Earl
    - Vinay Nair
    - Paul Conway
- **HRSA Staff**
    - Jim Bowman
- **SRTR Staff**
    - Katie Audette
    - Sally Gustafson
    - Bert Kasiske
    - Bryn Thompson
- **OPTN/UNOS Staff**
    - Chelsea Haynes
    - John Archer
    - Betsy Gans
    - Leah Slife
    - Shannon Edwards
    - Liz Friddell