OPTN/UNOS Kidney Transplantation Committee
Meeting Minutes
February 27, 2017
Conference Call

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

Introduction

The OPTN/UNOS Kidney Committee met on 02/27/2017 to discuss the following agenda items:

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

Welcome and Announcements

The liaison to the Kidney Committee, welcomed the participants and conducted roll call. The Committee Chair commented that they are about halfway through the Committee presentations. He thanked those who had already given their presentations, and he encouraged those who had not yet given their presentations to pay close attention to feedback to help them better prepare and orient themselves going forward. The recommendations that will be brought back to the Committee are going to be in the hands of the sub-committees that have been working on the procedures and consent documents for the last few months.

1. Improving En Bloc Kidney Allocation Project

UNOS staff provided an update on the en bloc proposal. The Work Group will reconvene in April to fully evaluate public comment/feedback and determine at that time what, if any, changes should be made. They will then vote and make a recommendation to the full committee on the changes and whether the proposal is ready to proceed to the Board of Directors' meeting for consideration in June.

Summary of discussion:

To date feedback has been mostly neutral or favorable. There are some regeions or entities that have yet to be heard from. There have been four regional meetings to date. Regions 4 and 7 oppose the proposal, and Regions 10 and 11 approved. Four committees have heard the proposal today including Minority Affairs Committee (MAC), the Transplant Coordinators Committee (TCC), and the Transplant Administrators Committee (TAC). They have all been neutral. The Pediatric Committee voted to support the proposal. Feedback has not been received from the societies yet. UNOS staff asked the participants to contact them if there were additional societies or advocacy groups that should be asked for feedback. There are seven regional meetings to go and four additional committees that will hear the proposal.

To date, there have been a lot of questions around the provision for splitting kidneys. It's not a part of the en bloc proposal but is actually a stand-alone policy that currently exists and is in effect, Policy 5.9. Almost all feedback has indicated that the accepting center should keep the accepting kidney or at least keep it local. The UNOS staff recommendation is to keep the provision as is, which they view as being the most equitable, transparent, and in keeping with current policy. Furthermore, the Work Group felt strongly about including a provision to mitigate gaming. The committee could mandate that kidneys be transplanted en bloc, which would likely not be a popular change, as it may dictate decision making on behalf of the surgeon. One of the regions brought up split liver language. That policy was reviewed, and the language is a little soft. Policy 9.8.a was also reviewed, which is a variance for segmental liver transplantation. It

has a little bit more structured language. If changes are made to that part of the policy proposal, it would have to go out for a second round of public comment.

Another theme is that no one likes the option to allocate singly or en bloc for the 15-25kg donor weight range. The options are to keep it as is, eliminate it all together, or determine a way to allocate kidneys individually first for that weight range and set up some criteria about when they could switch over to en bloc. The en bloc Work Group may opt to eliminate it. In terms of the weight ranges for the mandatory en bloc allocation, a wide range of suggestions have been made. The most consensus has been around 15 kilograms, which is what is being proposed.

Additional comments from committees and regions were shared for consideration. Several data questions have been suggested, such as whether the Work Group looked at kidneys from donors less than 25, the numbers that were discarded or unrecovered. There is not data on the number of en blocs that were split, which has come up. There also is not discard data on single kidneys from a split en bloc. There was some concern over the vulnerable kidney if an en bloc kidney is split, increased cold ischemic time, high risk of discard, and centers not accepting a released kidney for a split by another center. The Committee considered kidney size versus donor weight as a driver for allocation, and there's some concern about masking KDPI, as that takes away some predictive information from coordinators and surgeons when they are evaluating offers.

For the remaining regional prep calls, a recap of recommendations will be provided to the participants. After the Region 4 and 7 meetings where the proposal was opposed, the strategy was changed a little bit, and it may help to preface presentations by reiterating that the donor weights proposed are still up for debate and approving the proposal should not be dependent on whether the region agrees or disagrees with the weight thresholds. In addition, Policy 5.9-released organs is not part of the proposal and is not something new being proposed. It's not up for debate at this time. It may be helpful to print and provide Frequently Asked Questions, which are updated after each presentation. If the region doesn't like one part of the proposal whether that is splitting kidneys or something else and it looks like it may get voted down, UNOS staff suggested that they should propose an amendment if the counselor does not. In Regions 4 and 7, the counselor attempted to see if the floor would be amenable to an amendment. The problem was no one could think of what that amendment should be. Proposing an amendment helps gain support as opposed to the whole thing being voted down.

Finally, UNOS staff commented that they should not be afraid to reach out to staff or Committee leadership if they have any questions prior to the presentation. In April, the Work Group will reconvene to discuss the public comment feedback and determine if they want to make any changes. They will vote on a recommendation to the full Kidney Committee. The full Kidney Committee will then review those recommendations and vote whether to approve the final policy language and to send the proposal on to the Board of Directors for consideration at the June meeting.

One Committee member indicated that one of the most debated objections was the policy of released organs, 5.9. The people in the room generally understood that it was a standard policy, but the concern was there were special circumstances associated with the organs that made it less desirable. The people who spoke the loudest also objected to the 15-kg threshold. They really wanted a 10-kg threshold because they found they were doing very well with the smaller donors and singles. The final consistent concern was that they didn't like the optional pathway. It was explained that the KDPI is blinded for the original recipient because they are going to take the kidney. The second kidney then gets released according to policy and has to be released according to the local match run based on the calculated KDPI of a single organ because that's exactly what it is. In terms of the argument that "somebody else split it", the Committee Chair

commented that somebody is splitting the kidneys all of the time when they are retrieved and packaged. It's not a matter of size. It's a matter of technique. If there is an argument about the weight, one should find out how the policy could be amended so that it would pass. There is strong support from the OPO community, and as presentations are done, it's good to emphasize that.

Another member mentioned that in his region it was helpful to mention there is 100% PRA national sharing and that Policy 5.9 was already in existence. He further commented that if no one else wanted the kidney, it could potentially stay where it was split, but he did not bring that argument up to the region. He was questioning whether that was logical. The response was that from a surgical perspective the decision to split the kidney is made very early in the process. While the first transplant is done, which is going to take a number of hours, the OPO is trying to place the second kidney. If after 6 or 8 hours, many OPOs will revert back to the original center in an attempt to get a kidney placed. The Vice Chair commented that the real message is trying to balance between en bloc users and single users. What can be said is that a lot of the centers that use a very small kidney were well represented and were very comfortable with the current plan to allow centers to do en bloc at a little bit higher kilogram weight so that opportunities were not taken away from the centers that were comfortable doing small singles and splitting. Many of the centers that are going to split and do singles may be the only centers in their DSA. It's a very small number. In addition, it's a small number of en bloc kidneys in general, less than 2%. The policy represents a compromise.

The member continued to say that a couple of surgeons in his region raised concerns about pediatric recipients knowing it would go to Sequence A when they're given en bloc. The Chair noted that a pediatric recipient goes up to age 18. The kidneys are not allocated as splits, they are allocated as en bloc, and it's the surgical expertise and experience that is going to say I can use this as a single in this recipient knowing that there may be a potential for thrombosis. Sequence A isn't only pediatric recipients. It is some of the high EPTS score patients. It's important that they see the offers, which they were not seeing previously because the KDPIs were too high.

2. Improving Dual Kidney Allocation Project

UNOS staff presented the dual kidney allocation policy project. The decision has been made to transition the dual kidney concept paper portion to an update only at the regional meetings, so it doesn't invite feedback of any kind. The purpose of the update is to encourage the community to read the concept paper and comment. Through meetings they have found that the high-level meeting style update or overview of the concepts actually invites more confusion. There will be another round of public comment in the fall so the community will have ample time to review and comment on the final concept.

Summary of discussion:

The Dual Kidney Allocation project has been presented at four regional meetings with seven to go. It has also been presented to MAC, TAC and TCC. On Wednesday, a presentation will be made to the OPO Committee. Ops and Safety Committee is the final presentation.

Overall, there is not clear consensus on any one concept. Public comment for all proposals has been light to this point. The societies generally come in at the last minute to make comments. In addition, comments are likely to be posted following the presentations to the committees. Committee leadership will reach out directly to the the top seven high-volume dual centers and request feedback.

The most common questions and confusion is over split kidneys and Policy 5.9 for a lot of the same reasons as in the en bloc kidney project. There was also a comment on the potential

negative impacts on the released kidney. The Work Group considered the potential negative impact on the released kidney, but the net impact of the policy on the total number of transplants should be positive.

There was a comment that it is a concept paper, which means that it is not a policy that needs to be discussed. The discussion will come in the fall. The overall tone of what was trying to be done was to identify underutilized kidneys at both ends of the spectrum - en blocs and the small donors, and the most challenged donors on the other end that really have not fit into the revised KAS system. The goal is to fill in some of the gaps and help increase utilization of these types of kidneys.

UNOS staff summarized the comments they have received thus far. One member of the Work Group from a high volume dual center commented in favor of Concept 2.2. She provided additional comments for the participants to look through from other committees.

Next steps

- Public comment closes at the end of March. The Executive Committee will review and hopefully approve the proposal. The final concept will go out for public comment this fall, July 31st to October 2nd. There will be a review and vote on the proposal at the October in-person meeting. It will go up for the Board of Director's review and approval in the December meeting in Richmond. Then they would move on to implementation.
- Ideas for future initiatives are posted on the SharePoint site. OPTN goal alignment is very important. There are a lot of projects in the pipeline that are looking to increase the number of transplants. We are also trying to look at allocation, safety, and overall efficiencies.

Upcoming Meetings

- March 20, 2017, Chicago, IL
- April 19, 2017, Teleconference
- May 15, 2017, Teleconference