Meeting Summary

OPTN Operations and Safety Committee Meeting Summary September 26, 2019 Conference Call

Michael Marvin, MD, Chair Christopher Curran, CPTC, CPTBS, CTOP, Vice Chair

Introduction

The OPTN Operations and Safety Committee (OSC) met via Citrix GoToMeeting teleconference on 08/29/2019 to discuss the following agenda items:

- 1. Proposal to Eliminate the Use of DSA and Region in Kidney Allocation Policy Kidney Committee
- Proposal to Eliminate the Use of DSA and Region in Pancreas Allocation Policy Pancreas Committee

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

1. Proposal to Eliminate the Use of DSA and Region in Kidney Allocation Policy – Kidney Committee

A representative from the Kidney Committee presented their Proposal to Eliminate the Use of DSA and Region in Kidney Allocation Policy to the Committee. Members provided feedback and voted on their sentiment of the proposal.

Summary of discussion:

A member stated that at the Region 11 meeting, there was a lot of negative feedback addressing that the issue that should be addressed is OPO performance rather than kidney allocation. It is suggested that there should be a smaller distribution circle so that it will have less impact and this should be rolled in.

The Kidney Committee Vice Chair stated that in terms of the OPO performance, there had not been any data reviewed suggesting that the way to fix geographic disparities is at the OPO level. It is believed that there are other factors than just OPO performance that is resulting in a 1.5 - 10.5 year wait time variation. The Kidney Committee did look at smaller distribution circles and in terms of a roll in, this would be extremely difficult. The OPTN has discussed a 1 year – 18 months time period to get all of the programming done to have this allocation change to happen.

A lot of the initial feedback received was in favor of continuous distribution. The reasoning was that if DSA and region are being eliminated, the use of circles should not be used. The Kidney Committee felt that switching completely to continuous distribution would be more of a shock to the system. The proposed allocation policy was believed to be a more rational roll out.

The member continued that unlike a thoracic organs, which are likely flown by a private plane or helicopter, most kidneys will be transported by commercial flights. The distance should be a factor of what the projected cold time would be rather than the distance from the hospital. There is a sense in the southern regions, there would be a lot of shipping to places where more organs have been listed. This affects the list but not the burden of kidney disease in an area.

The Committee Chair stated that at the Region 2 meeting, there was a disapproval of this proposal as it stands. The circles are too large for the major metropolitan areas even with the proximity points. The

fundamental problem with all of the allocation discussions is that none of the discussions have included costs. Smaller circles would address the acute mandate in eliminating DSAs. The mandate is to eliminate DSA and it is suggested to begin with a smaller circle and then evaluate the behavior.

The Kidney Committee Vice Chair asked members to be more specific of what size circle the Committee was proposing.

A member stated that they agreed with using a 250 NM circle since there had been some modeling. The increases in Kidney-Pancreas (KP) did not make much sense. Although this was modeled, pancreas is limited by the number of candidates and not by the organs. The overall net effect on kidney was negative and it was only modestly negative because of the increasing KP's, which was widely doubted. A smaller circle would be a good step and would meet the requirements of eliminating DSA's.

The Committee Vice Chair stated that the disparity is not strictly about OPO performance but instead about the pool of potential donors vs. the size of the waitlist. For emergency kidney candidates, there is the hope that these candidates would have access to compatible blood types and not just identical bloody types so that these candidate would have a greater change to receive a transplant in the short time period. There was concern raised regarding the import backup using a 150 NM circle. If the importing OPO is the organization that bears the responsibility for reallocation, it may mean that within that 150 NM, those organizations are allocating are allocating to multiple other DSAs. It would make sense to have the host OPO to be the allocator in the backup circumstance. Additionally, if an organ is being allocated to another DSA without specimen to do crossmatches, this is asking for a lot of difficulty and challenges for that accepting program to get their own crossmatch done on a kidney with potentially significant ischemic time. It would make sense to consider enabling some flexibility that the host OPO could have in allocating to either the center directly or to centers that are served by the same tissue typing lab. This could also be in collaboration with the host OPO and recipient OPO.

The Vice Chair continued by suggested that there should be some restrictions set for reallocation to backups. There should be restrictions on who those back up candidates to avoid allocations to highly sensitized candidates within a certain area to prevent discards.

The Kidney Committee Vice Chair asked how this would be operationalized. The Vice Chair stated that when there is ischemic time, there needs to be a more strategic approach to candidates who are more likely to receive the kidney rather than go through patient who may not be realistic candidates if they are highly sensitized or other circumstances.

UNOS staff called for a vote.

VOTE: Strongly Support 10%, Support 20%, Neutral/Abstain 0%, Oppose 60%, Strongly Oppose 10%

Next steps:

The comments received by the Committee will be synthesized into a formal statement that will be submitted for public comment.

2. Proposal to Eliminate the Use of DSA and Region in Pancreas Allocation Policy – Pancreas Committee

The Pancreas Committee Chair presented their Proposal to Eliminate the Use of DSA and Region in Pancreas Allocation Policy to the Committee. Members provided feedback and voted on their sentiment of the proposal.

Summary of discussion:

A member asked that if there was a belief in the kidney modeling with the pancreas increase. It would be very hard to defend a system that decreased overall transplant.

The Pancreas Committee Chair stated that logistically, it is not believed that there would be a lot more KP transplants as predicted because currently KP's are not seeming to travel from outside of 250 NM much. In this specific proposal, the 500 NM circle would be the local circle in which the pancreas would follow the kidney. The organs would stay together first inside the circle. It is being foreseen that the KP increase is an over model and that there would probably not be a drastic of an increase in KP transplants which would return kidneys into the pool. Overall, it would not change the modeling of total number of kidney transplants performed. Another thing in the modeling is that all the match runs are cut off at 200 organ offers.

The Vice Chair stated that right now when an OPO is allocating a pancreas down the KP match run, once getting past the local, there is the ability to uncouple the organs. Is the intent that this would occur after the 500 NM?

The Pancreas Committee Chair confirmed that this was correct. The kidney and pancreas would be offered together within the 500 NM. If an offer is not accepted, it would be offered out. It is believed that there will be less use of facilitated allocation because there are probably more aggressive transplant centers within each 500 NM radius. There will be so many patients listed inside the circle that it will be rare that the organs would need to be uncoupled and offered out farther.

The Vice Chair continued by asking how often is a pancreas that goes out of DSA that is then declined is reaccepted someplace else? There should be specific monitoring to make sure that programs that import KP's do not then decline the pancreas as a way to draw the kidney.

The Pancreas Committee Chair agreed with this and stated that current and future policy both state that if the KP cannot be used in the intended recipient and the kidney is wanting to be used should be communicated with the host OPO of these intentions because the kidney still belongs to the host OPO. That rule would not change and the monitoring that is in place would stay.

The Pancreas Committee Chair stated that it is not fairly common for a pancreas to be turned down and reaccepted elsewhere. Most times, the pancreas is accepted within the same program. The kidney, on the other hand, could travel back to the host OPO if needed for reallocation.

The Vice Chair asked if the policy could support not only the 150 NM, but the OPO and transplant program having the latitude to back up the organ within their program rather than a requirement to reallocate. This may be a component that enables more utilization and less waste of pancreas.

The Pancreas Committee Chair agreed with this and stated that this information would be taken back to the Pancreas Committee.

UNOS staff called for a vote.

VOTE: Strongly Support 0%, Support 60%, Neutral/Abstain 20%, Oppose 20%, Strongly Oppose 0%

Next steps:

The comments received by the Committee will be synthesized into a formal statement that will be submitted for public comment.

The meeting was adjourned.

Upcoming Meeting

• October 24, 2019 (In- person meeting)