Introduction
The Policy Oversight Committee met via teleconference on March 21, 2018 to discuss the following agenda items:

1. New Project Review
2. POC Public Comment Review Debrief and Feedback
3. Update from the Ad Hoc Geography Committee

The following is a summary of the Ethics Committee’s discussions.

1. New Project Review

Overview
There was a fair amount of consensus in the feedback, and the goal was to get approval and move forward to evidence gathering.

A. Improving Access for Pediatric & Highly Sensitized Kidney Candidates

The Committee did make a recommendation on the survey; 8 voted in favor, 1 voted no, and 3 voted maybe to proceed. There was some concern about the ambitious timeline. There has also been feedback about collaboration between the Pediatric and Kidney Committee, and since the surveys were done there has been additional communication between the leadership of both committees about how to collaborate on the project. The POC has recommended a few different projects that are before the Executive Committee for approval. If the Executive Committee approves the two projects, the proposed alignment was presented. A committee member commented that they had a lot of feedback from the Pediatric Committee. The Committee strongly supported the problem as stated by the Kidney Committee. They did note that there would be benefit to improving the proposal if there had been more lead time for collaboration. Marian, who was one of the no votes originally, commented that what has happened in the meantime with collaboration has been strengthening, and she would support it going forward.

A vote was taken, and by unanimous vote, it will be a Goal 2 project.

A vote was taken to recommend approval to the Executive Committee, and it passed unanimously.

B. Modify the Data Submission Policies (DAC)

This has been a long-standing request of both the community and staff who work on the policies. There was overwhelming support from the survey; 12 in favor, 0 no, and 1 maybe.

A vote was taken, and by unanimous vote, it will be a Goal 5 project.
A vote was taken to recommend approval to the Executive Committee, and it passed unanimously.
2. POC Public Comment Review Debrief and Feedback

Overview

The OPTN/UNOS President provided information regarding the POC public comment feedback. What is critical to understand about the process is the normal pathway is followed about 99% of the time, but about 1% of the time they have to go down the emergency pathway. The emergency pathway cannot be taken unless there is imminent patient danger, regulatory authority, or issues of significant risk. The lung situation met the criteria of regulatory authority. HRSA was sued by an individual patient, and they were asked to tell the Justice Department lawyers who were involved whether or not there was a defensible position for using DSA first. Had the secretary given a direct order to change the policy, the post hoc call for public comment would not be able to be issued. Nor could they easily amend the policy that came down by secretarial order if there were unintended consequences. Some lessons have been learned. Some of the ways that communication is handled need to be changed. The emergency pathway process expires November 23rd of 2018, and it reverts back to the original DSA first if they don't pass what got implemented at the board meeting. There is some threat to doing that, however, if the determination is made that it didn't follow the final rule and they could go out to the larger zone. Data is being actively collected and will be presented to the Thoracic Committee and more widely.

In terms of the role of the POC in the emergency pathway, a lesson has been that they could have been a better job of letting the POC know more quickly. Another learning was that they didn't do a good job of explaining the emergency pathway and why it had to be taken. More robust notification trees are being developed with UNOS staff for emergencies as well as things like the liver redistribution proposal. There is a communications director position that is open and is being actively recruited for.

The actions and role of the members of POC were inferred but not made specific. There's not a time that the chairs routinely meet but POC does. The expectation is that the members of POC will be the amplification for what comes to the POC.

Questions/Discussion

A question was raised as to when the Judge required a one-week response and what would have happened if there had not been a response. The membership was somewhat puzzled as to why it wasn't appealed or defended more vigorously. The president explained that when the lawyers went for the appeal the time got shortened. When they looked at DSA as an allocation unit and compared it to the Final Rule, there wasn't a rationale for the priority of DSA. It's not like a nautical mile circle, and it wasn't as defensible. What could have happened is the secretary could have simply said, OPTN, you must change the rule at which point it wouldn't be able to be sent back out for public comment. If there hadn't been a response within the one week, there would likely have been a mandate to change the policy. It was then suggested that it must be a relatively weak policy if it can be overturned within seven days with no input, and the question was raised about how they could make sure other policies are not similarly vulnerable. The president explained that is exactly what they are doing with what Dr. Niederhaus was going to present next looking at geographic principles.

The president urged committee members to work with their regional administrators to write something, put it on the public comment website, and that feedback will be taken into consideration before putting something out that POC will see first. It will require a bylaw change and will come out for the formal public comment cycle at some point.
3. Update from the Ad Hoc Geography Committee

Overview

The vice chair of the Pancreas Committee, presented what they have been doing on the Ad Hoc Geography Committee. The Committee was formed in 2017 at the Board of Directors' meeting after the emergency pathway was accessed to begin to question whether all of the allocation happens in a way that is consistent with the Final Rule. The Committee's charge is to establish defining guiding principles for the use of geographic constraints in organ allocation, to review and recommend frameworks and models for incorporating geographic principles into allocation policies, and to identify uniform concepts for organ-specific allocation policies in light of the requirements for the OPTN final rule.

The Committee does not plan to tell other committees what to do and has no intention of changing any allocation policies. It also does not intend to send any proposals for public comment and does not want to work in isolation. The Committee will be discussing the models and frameworks that could be used to guide organ distribution and align the frameworks with principles so that there is consistency with the considerations and principles. A report will then be issued to the Board of Directors with recommendations. The Board will then decide on the next steps.

At this time, the Committee is giving consideration to geographic principles, and apart from the principle statements there are considerations that must be taken into account when discussing organ distribution. The Committee will be taking into consideration organ system resources and utilization. The Committee has worked on gaining consensus on the top principle statements after discussing and scoring approximately 20 potential statements related to organ distribution.

Questions/Discussion

Clarification was asked for on the separation of addressing distribution but not allocation. There would clearly be an impact in both directions. Chad commented that it is something that the committee needed to work through, and they remind themselves continually to focus on the organ distribution part. Organ allocation encompasses much more than just the models of geographic organ distribution and involves topics like the match run process, specific organ differences that drive allocation tables or allocation classifications. It involves candidate priority in how each organ determines the priority of candidates, things of that nature. So allocation includes all of that stuff, but when reviewing principles, frameworks, and models, the committee’s focus should be on just geographic constraints of organ distribution not all of those other things. The goal will be for individual committees to look at their allocation for specific organs to see if the principles apply to that and if not what can be done to put them back into alignment.

A summit type meeting is being planned where OPO performance, center performance, and systems improvement groups will be together to take a deeper dive into some of the areas of policy.

A question was raised as to whether the Geographic Committee will be looking at the alignment of where some of the boundaries lie, which are very arbitrary and based on old models of transplants. The Pancreas Vice Chair didn't think that was the charge to the committee, and she explained that they are kind of like the Ethics Committee looking at how to incorporate the final rule of equity and utility while at the same time trying to figure out what is working in distribution of organs and what is not. Some of their recommendations may guide away from the current maps. On the other hand, it is not the committee's job to make any changes. That would come down the road after the Board hears the guiding principles.
Upcoming Meeting

- Wednesday, March 21, 2018, 3:30 PM ET
- May 7-8, 2018 Spring in-person meeting, Richmond, Virginia