OPTN/UNOS Policy Oversight Committee
Meeting Minutes
July 31, 2018
Conference Call

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Introduction

The Policy Oversight Committee (POC) met via teleconference on 07/31/2018 to discuss the following agenda items:

1. Welcome and Attendance
2. Public Comment Proposal Review
3. Geography Update
4. Geography Projects Review

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

1. Welcome and Attendance

Attendees were welcomed to the meeting and the agenda was reviewed.

2. Public Comment Proposal Review

Survey summary:

The primary function for the POC's review of a public comment proposal is to validate whether it meets the standards for policy development and if it is ready for public comment. A good amount of feedback was received on the 6 public comment proposals before the POC. The POC strategic plan was briefly presented, showing the level of effort of each committee project across strategic goals. The 6 are smaller projects with later maturity dates.

Summary of discussion:

The three proposals were placed on the consent agenda because they got high scores and received all yes votes as far as readiness to go to public comment:

- Changes to islet bylaws (Pancreas)
- Pancreas program functional inactivity (Pancreas)
- Addressing HLA typing errors (Histocompatibility)

A vote was made: Do you recommend to the Executive Committee that the 3 proposals on consent agenda be approved for public comment?

100% yes; 0% no; 0% abstained.

Three proposals received slightly lower scoring or received one or more no votes up for further discussion of comments:

Change to Hospital-Based OPO Voting Privileges (MPSC)

There are some hospital-based OPOs that do not have an independent vote from the associated hospital transplant program. The proposal is for those hospital-based OPOs that meet certain criteria to be eligible to vote.

Some specific comments were addressed. There is adequate description for requirements for separation. MPSC considered this carefully and the OPO would report up through the hospital board, but not the director. There was a suggestion that hospital-based OPOs provide documentation on an annual basis to verify the separation, which is reasonable. The OPO director shouldn't report to anyone with a direct leadership role in the transplant program. Leadership roles in each organization were discussed by MPSC and how they should not cross-over. Language in the proposal was tweaked to reflect this. No conflicts of interest were identified. It was determined the hospital-based OPO's votes would not carry defining weight in their area, but give them the independent voice they want.

One comment was on the importance of the reporting structure. Perhaps the clarification could be something along the lines of "as long as the OPO director does not report through the same structure."

A vote was made: Do you recommend to the Executive Committee that the Hospital-Based OPO Voting Privileges proposal be approved for public comment?

100% yes; 0% no; 0% abstained.

Tracking Pediatric Transplant Outcomes Following Transition to Adult Care (Pediatric)

The proposal is not a policy change, but guidance only. One comment was the guidance document was really on transitioning care and the actual guideline didn't seem to talk about tracking pediatric transplant outcomes specifically. As the project evolved over time, the emphasis is not on getting the data, but to encourage that there be a process to have the recipients engage with a transplant provider for ongoing care. The emphasis is on the transition period of on-boarding self-care responsibility in teenage years and then the transfer process. Members may not choose to vote because the title is a bit misleading. It needs to be plain language so it is very clear, and this will be modified by the Pediatric Committee.

Some specific comments were addressed. There was a theme requesting more details on information sent from the pediatric transplant program to the adult provider. The plan has always been to provide more detail following public comment and clarity about ongoing communication with the pediatric transplant program providing recipient health information for data reporting. There needs to be an ongoing relationship to share this information over the life of the functional graft of the recipient. It is up to the hospital to determine whether to implement and to what degree to implement the guidance. Lost to follow-up rates will be tracked to see if the guidance may have had an impact. Health information exchanges might enhance the resource-intensive process that sometimes transplant programs need to pursue health information on recipients that are at another facility. The staff at those programs would know how to best make that fit.

One question was whether there were any true objectives that could be met to add some requirement for a peds program. The document is not meant to include specific rules, as it is guidance only.

A vote was made: Do you recommend to the Executive Committee Tracking Pediatric Transplant Outcomes Following Transition to Adult Care proposal be approved for public comment?

86% yes; 14% no; 0% abstained.

One vote was for yes, presuming the title will be changed.

Frameworks for Organ Distribution (Ad Hoc Geography)

The Final Rule contains two provisions related to organ distribution and geography: organs are to be distributed over as broad a geographic area as feasible and allocation policy should not be based on a candidate's place of residence or place of listing except for the other reasons listed in the Final Rule.

There was litigation regarding use of DSAs in lung and liver allocation. DSA is used across all organ types, so changes to those distribution systems will be made proactively before litigation. The OPTN wants the transplant community to be able to make the changes, rather than legislature making the changes.

The changes being proposed must be backed by evidence and in compliance with NOTA and the Final Rule, not just by consensus.

One comment was that it would be helpful to know what the next steps are for implementation and if there are any different estimates to resources/costs for each of the three proposed strategies. Specific details and steps are yet to be determined, which may be dependent on the public comment and direction chosen in narrowing down the three frameworks to one. Modeling will be done regarding resource utilization and cost.

A vote was made. Do you recommend to the Executive Committee that the Frameworks for Organ Distribution proposal be approved for public comment?

100% yes; 0% no; 0% abstained.

3. Geography Update

Data summary:

The five Principles of Geographic Distribution were approved by the Board of Directors, as well as the 3 geographic frameworks were approved by the Board for public comment.

The 5 principles each align with a component of the Final Rule. Three geographic frameworks were narrowed to 3, with the goal of identifying a single framework which will eventually be used across all organ types. The three frameworks are described in more detail.

- Fixed distance from Donor Hospital. This would be a series of concentric circles centered around the donor hospital, including one or more transplant programs. Advantages are easy to explain and the first distribution is not limited to the smallest circle. This is the current model being used in lung. Disadvantages are it still uses fixed boundaries and differences in population density will affect patients in different ways.
- Mathematically optimized boundaries. This would use an algorithm to come up with the boundaries. It might be a large number of localized neighborhoods or a limited number of large districts. Advantages are it provides consistent results and can be scaled as needed. Disadvantages are that the boundaries may be complex and it would be difficult to explain, as well as it still uses fixed boundaries.
- Continuous distribution. This is also known as distribution without boundaries. Every candidate on a waiting list for a particular organ would be considered a potential recipient of that organ based on a composite score, composed of a proximity score and a medical priority score that includes considerations like pediatrics, high CPI rate, etc. Advantages are two patients similar in suitability would be treated in much the same way and more likely organ offers would be matched efficiently with candidates in the highest medical need. Disadvantages are is more difficult to explain and understand and it may not produce concentrated matches.

The timeline is that all the organ-specific committees will work towards the goal of modeling requests to SRTR in the fall, with policies developed for public comment in Spring 2019 and consideration by the Board in June 2019. Liver is ahead of the other organs in the timeline.

The Liver Committee proposal will go through special public comment in Fall 2018 and the other organ-specific committees are beginning to do their work. The goal is for all organ policies to eliminate DSAs and regions as units of distribution. The Geography Committee will continue to meet monthly and will continue its role in monitoring progress providing guidance and oversight of the committees as needed.

Summary of discussion:

There was a request for clarification on the goal of one framework of distribution across all organs. This a longer-term goal not part of the expedited timeline. The work being done by the committees now should keep in mind the ultimate goal of allocating organs in a way that is rationally determined and consistently applied, thereby eliminating DSAs and regions as units of distribution. For example, with the fixed distance, each policy would use circles, but there may be variations on circle sizes that are organ specific. Specific rules and variables will vary depending on clinical indications for the different organs. The Board will decide on the final framework that will be used, but any of the models could be brought into alignment over time.

The concentric circles framework refers to the donor hospital, but that is no longer the primary recovery site for some organizations. The center of the circle will be the hospital where the donor originates, rather center where the recovery takes place or in other words, the recovery hospital rather than the procurement center. This is how liver is being modeled, but this is one of the components that will be consistent across all organ systems.

One suggestion was that the frameworks be vetted out to groups that are in opposition. Data is being compiled including video and audio detailing the frameworks, which are available on Transplant Pro. There will be a series of webinars to allow for the opportunities to ask questions, as well as the public comment period. In addition, all members of the Geography Committee (including chairs and co-chairs of organ-specific committees) are reaching out to the community to make them aware.

4. Geography Projects Review

After an overview of the various geography projects, the POC then discussed whether to approve the four new geography projects.

Eliminate Use of DSAs and Regions in Kidney and Pancreas Distribution

Comments centered around concern over the expedited timeline of the project. The members are doing the best they can, given the rapid timeframe.

A vote was made. Do you recommend to the Executive Committee that the Eliminate Use of DSAs and Regions in Kidney and Pancreas Distribution project be approved for public comment?

92% yes; 0% no; 8% abstained.

Eliminate the Use of DSAs in Thoracic Distribution

Heart allocation had recently been approved to be changed, so DSA is being removed from the framework that has not been quite implemented so it can be fully implemented. No negative comments were made on this proposal, other than the repeated concern over the expedited timeline.

A vote was made. Do you recommend to the Executive Committee that the Eliminate the Use of DSAs in Thoracic Distribution project be approved for public comment?

93% yes; 7% no; 0% abstained.

Eliminate use of DSAs and Regions in Liver Distribution

There are two different allocation policies that remove DSA and Region that are being modeled. Comments once again centered around the expedited timeline and concern that it will be done correctly, as likely is resulting in medical issues being ignored. There was also a comment that since the changes are being made due to legal pressure, there may be legal action taken by individual members to push back on the policy changes.

A vote was made. Do you recommend to the Executive Committee that the Eliminate use of DSAs and Regions in Liver Distribution project be approved for public comment?

70% yes; 30% no; 0% abstained.

Eliminate Use of Regions in VCA Distribution

The comment was made that geography doesn't seem to affect this field. The VCA committee is committed to removing regions in a deliberate way using available data.

A vote was made. Do you recommend to the Executive Committee that the Eliminate Use of Regions in VCA Distribution project be approved for public comment?

77% yes; 13% no; 0% abstained.

There was acknowledgement that there the normal robust analyses of projects have not been performed before coming to POC, which is of course due to the rapid timeline. The important thing will be to keep the community informed and engaged in the process. One point is the true impact on the overall cost of transplantation must be weighed in on the overall utility of what is being done. There may be some downstream effect on transplant programs that are spending twice as much to do the same volume of transplant.

Several Committee members on the call today expressed their frustration and anger with the expedited timeline and the lawsuits being the driver of the changes.

Upcoming Meeting

- August 28, 2018, 4 pm ET
- September 25, 2018, 4 pm ET
- November 2, 2018, in-person meeting in Chicago, IL, 8:30 am to 3 pm