OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

OPTN Policy Oversight Committee
Meeting Minutes
May 10, 2015
Richmond, Virginia

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Introduction

The Policy Oversight Committee (POC) met in Richmond, Virginia on 05/10/2019 to discuss the following agenda items:

1. Setting Policy Priorities
2. Policy and Community Relations Update
3. Review of Current Portfolio

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

1. Setting Policy Priorities

The Organ Procurement and Transplantation Network (OPTN) presented on contract changes, the evolving role of the POC, project review procedures, and potential policy priorities. OPTN staff sought feedback from the members of the POC.

Summary of discussion:

- OPTN Contract Changes

OPTN staff explained that the new contract calls for six operating committees of the Board of Directors (BOD). The remaining committees function as policy development committees. Currently the POC's role is to advise the BOD, prioritize OPTN policy development activity, coordinate policy issues, and justify policy compliance with the National Organ Transplant Act (NOTA) and the Final Rule.

- The Role of the Policy Oversight Committee

The new vision for the POC is to have the committee identify aligned policy priorities within the portfolio of projects. This will allow the OPTN to take on larger issues as a whole. The transition to this model will involve identifying policies with potential for modification 12 to 18 months before BOD meetings. This would send policies through the public comment process in a coordinated way.

The OPTN sought feedback at this time. A member inquired as to how this new model would change the work of the committees and how small projects that do not align with larger policy priorities would function. OPTN staff responded that this new model is not meant to be exclusive and that committees may carry on with their community projects. The goal is to streamline projects that are resource intensive or do not provide significant value to the transplant community. The new POC model would not stop committee work, but would solicit ideas from committees for larger policy movements.

A member noted that when he is asked to review projects from an organ specific committee outside his scope, he feels uninformed and oftentimes rubberstamps these projects. He attributed the high project proposal approval rate to situations like these. This member recommended developing groups of interested and informed stakeholders to vet specific projects within their scope of knowledge and identify projects that would be impactful. He suggested developing organ specific think tanks to create structure and direction in the review process.

OPTN staff reported that over 90% of proposals that go to POC & ExCom are approved. Currently the funneling of projects assists in their prioritization, but moving forward the POC looks to call better upon the clinical and operational knowledge of its committee members. OPTN staff reported that leadership can work with each of the individual committees to uncover community wide issues and to form larger strategic policy priorities.

A member commented that the plan looks good for projects that start with stakeholders, but that this is not always the case. This member also promoted more transparency and communication from the BOD. Another member asked how other committees can be involved from the get-go if the scope of projects is to be limited. OPTN staff answered that this approach will lend itself to an increase in cross committee collaboration.

The POC will help decide on starting points for larger issues, including intentional timing and planning. A member noted that the committee should take it upon themselves to initiate updates and information sharing. This will help larger initiatives move through the policy process at a faster rate. This member highlighted the opportunity the POC has to be involved in one another's projects and encouraged members to communicate on a more frequent basis.

A member noted her support for the big picture idea of larger drive and change, but was concerned about how POC would align with all five strategic goals if a large policy priority were to fall under only one goal. This member felt that POC may overload one strategic goal, while neglecting the others. A member replied that flexibility will be needed in the process. Priorities will overlap and over time the five strategic goals should become well balanced.

OPTN Staff asked for ideas on how stakeholder committees can be more involved. A member said that stakeholders would likely want to be involved in initiatives if they were to be engaged early on in the process. Other members agreed.

- Project Review Procedures

OPTN staff explained that part of the POC's role is to give feedback on whether or not a project is of high value to the community and aligns with the strategic plan. He stated that the overall goal is to identify and invest in the projects that will have the most benefit to the transplant community. The following discussion seeks to define what the transplant community considers high benefit projects. OPTN staff explained that urgency, willingness, breadth, and depth could be used to define benefit and show what POC values. Staff emphasized that a change in member behavior must occur in order make policy initiatives impactful.

It is important to know what POC values in terms of benefit quantification. OPTN staff polled members on what they value when defining benefit. These questions examined urgency,

willingness, breadth, and depth. POC was given a series of comparison questions and asked which of two options they found to be more valuable.

- Willingness of leadership vs. willingness of the transplant community?
    - Results: Willingness of the transplant community was strongly preferred.
- Breadth of all members vs. breadth of specific members?
    - Results: Mixed. Equal and breadth of all members moderately preferred.
- Ability to measure vs. ability to be innovative?
    - Results: Innovation moderately and strongly preferred.
- Breadth of all members vs. breadth of all patients?
    - Results: Patients preferred.
- Ability to measure vs. change in member behavior?
    - Results: Mixed. Equal and moderate/strongly preferred for member behavior.
- Innovation vs. changes in member behavior?
    - Results: Innovation strongly/very strongly preferred.
- Urgency vs. willingness (whether it be community or leadership)
    - Results: Urgency.
    - It was noted that this is usually the preferred answer when comparing these two elements of benefit quantification.
- Urgency vs. breadth?
    - Results: Moderate Urgency
- Urgency vs Depth?
    - Results: Urgency
- Breadth vs. Depth?
    - Results: Equally preferred with much variation.
    - A member commented that this one was the hardest, as it would be dependent upon the specific project.
- Willingness vs. depth?
    - Results: Mixed. Equal and depth strongly preferred.

A member noted the importance of understanding community values and standing by them when faced with tough decisions. This member asked how the POC would go about saying no to projects and if leadership would step up to make hard decisions.

Members agreed that the value comparison questions could have varying answers dependent upon the circumstances of a project. A member commented that the value of one project could change based on what else is going on in the community.

- Potential Policy Priorities

The POC was asked to think about what policy priorities they would like to take on at this time. A member suggested having a quarterly update on committee projects to keep the POC informed on opportunities for collaboration. OPTN staff asked how the committee would keep leadership involved with larger committee issues and in areas where knowledge can be expanded. A member commented that she would like the opportunity to give feedback and ask questions early on in the project review process.

The POC brainstormed on potential policy priorities. A member suggested examining access to the list, especially when a patient does not have insurance or lives in a state with a small transplant program. She recommended looking at national listing practices in order to check for consistency or lack thereof. A member responded that access to the list can be related to state insurance laws that the OPTN cannot alter. Another member suggested gathering data on patients who are or are not listed.

Another member brought up patient care from start to finish. She asked how patients can be treated in a more equitable way from diagnosis through post-transplantation. She called for a process that supports patients through the continuum of care.

A member reported that transportation should be a top priority due to broader sharing. This member called for policies with safety components in order to decrease risk.

A member discussed the impact of changing guidelines. He commented that sometimes the OPTN sends out guidance that might get in the way of how transplant centers and Organ Procurement Organizations (OPO) function. He called for the OPTN to focus on more efficient distribution. He reported the need for policies surrounding rules of engagement in the operating room and swift placements of late turn down organs.

POC members also mentioned the education of patients. Increased Risk Designation (IRD) and living donation were offered as potential topics. A member suggested developing education geared toward contracted individuals who work in transplant in order to develop a required standard of knowledge.

A member noted that all of these priorities could work together at once and produce a large successful change as opposed to individual committee change that would be disjointed.

A member asked how the POC could incorporate the protection of vulnerable populations into policy priorities. OPTN staff relied that projects should be examined for the potential to impact these populations early on for greater awareness.

A member wanted to discuss guidance for Multi- Organ Transplant (MOT). She reported that OPOs are seeing more MOT candidates and having to make hard decisions on how to prioritize and allocate organs with little guidance.

Next Steps:

This discussion served as an idea generating starting point. From here the POC can move forward with an understanding of their evolving role that aims to make greater policy movements.

2. Policy and Community Relations (PCR) Update

The OPTN gave updates on committees and governance structure, PCR staff restructuring, and geography projects.

- Committee and Governance Structure Update

Per the new contract, the OPTN Data Advisory Committee (DAC) is now an operating committee of the BOD and responsible for oversight of all OPTN data. DAC must provide an

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annual report to the BOD with recommendations for data improvement and seeks suggestions from POC and other committees. A member noted that the altering of data forms is a necessary, but challenging process. OPTN staff agreed and added that any changes must go through the Office of Management and Budget (OMB). Staff reported that the Health Resources and Services Administration (HRSA) said they will work with the OPTN through this process.

- Policy and Community Relations Update

OPTN Staff explained the restructuring of the PRC department. This restructuring aims to increase the flexibility and efficiency of staff. The roles of the transplant community administrators (TCA), policy analysts, policy associates, and administrative coordinators were explained to POC. A new team alignment has been established to best serve committees.

- Geography Project Update

The second round of kidney and pancreas distribution modeling is expected mid-July and will consist of 11 hybrid models. The general concern voiced during the last public comment period was that the modeling showed a decrease in the rate of transplants. A member commented that the modeling results did not seem realistic as it is hard to model behavior change. She firmly believes the rate of transplants will not decrease and that that the new modeling will be more representative of actual outcomes. OPTN staff reported that after one year of the broader sharing of lungs, the number of transplants has not decreased. Special considerations are being taken for Models 10 and 11 as mileage and proximity points inside and outside the circle could disadvantage some patients.

The OPTN discussed future plans for the continuous distribution of lungs including the release of a concept paper in the fall that aims to educate the community. Lungs are the first organ to transition to continuous distribution allocation. The OPTN has a high level project plan that addresses medical priority, efficiency, outcomes, and patient access.

Next Steps:

The kidney and pancreas committees will have in-person meetings followed by public feedback sessions. Kidney and pancreas will release separate public comment proposals with a target board timeframe of December, 2019.

The next steps for the continuous distribution of lungs is to examine travel mode and cold ischemic time as it relates to efficient allocation.

3. **Review of Current Portfolio**

OPTN staff presented a proposed project by the Operations and Safety Committee (OSC) and reviewed the current portfolio.

- Operations and Safety Committee

The OSC will work with DAC to gather data on the impact of broader distribution on transportation. A member noted that this project is an opportunity to use GPS tracking to gather data as organs are transported. Another member asked if this project would also investigate the cost of transportation. A member reported that cost may be hard to determine

due to inconsistencies within the market and OPOs. Unanimous support was shown to move forward with this project.

- Current Portfolio Update

OPTN staff gave an overview of current portfolio projects. He explained that there are currently over 200 ideas in the funneling system. The projects can be filtered by committee, key milestones, strategic alignment, and confidence level. The confidence level is determined by the OPTN policy analyst who works closely with the project along with the overall sentiment gathered during public comment. This centralized system documents committees' projected and actual project goals. A member requested the ability to access project data from the dashboard.

Next Steps:

The ExCom will receive the POC's recommendation then review the OSC transportation data project.

Upcoming Meetings

- June 25 (Teleconference)
- July 1 (Teleconference)