Discussions of the full committee on August 29, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov

Committee Projects
1. None

Committee Projects Pending Implementation
2. None

Implemented Committee Projects
3. None

Review of Public Comment Proposals
4. None

Other Significant Items
5. Committee New Project Review

Projects follow a relatively linear path before they are presented to the POC for project review. Staff collect project ideas from multiple sources: Committee members, Board members, HRSA, the public, etc. Ideas are assigned to a policy analyst to discuss with the leadership of the potential sponsoring committee. They discuss whether the idea is worth pursuing and the general priority of the idea. Some ideas won’t progress past this point. If committee leadership are supportive of the idea, and there are staff resources available, then staff and the committee will begin analyzing the problem; often times this requires the UNOS Research Department to review data in the OPTN data system. Once the committee understands the problem, has a concept for the solution, and agrees that it is worthy of resources, then the committee will prepare a project proposal for POC consideration.

Staff resources are not allocated for projects until the POC recommends approval of the project. After that point, the project is sent to the Executive Committee for approval and is prioritized for resources across the company. At this point, the project moves from analyzing the problem to evidence gathering. Generally speaking, proposals are also not permitted to proceed to public comment unless the POC and Executive Committee have approved the project.

For the five new projects presented to the POC, POC members completed a survey that asked questions regarding the quality of the problem statement, whether the proposal has evidence to support the problem, need for collaboration, development of project timeline, and primary strategic goal alignment.
The POC provided all comments about these projects that were entered as part of the survey to the sponsoring Committee and the Executive Committee for their consideration.

The POC used the results of the survey to make a recommendation to the Executive Committee regarding which 5 new projects should be approved to be part of the committee portfolio. The POC, after review of the projects, voted to make these recommendations to the Executive Committee:

- Ethical Considerations for Experimental Manipulations of Deceased Donor Organs (Ethics Committee) **Primary Goal 4 – POC recommends approval with on hold status until resources are available (unanimous)**
- Informing Potential Living Donors about Recovery Centers with Different Eligibility Criteria (Living Donor Committee) **Primary Goal 1 – POC recommends cancelling this project (15 No, 5 Yes)**
- Maximum Allowable BMI for Kidney/Pancreas Waiting Time (Pancreas Committee) **Primary Goal 1 – POC recommends approval with on hold status until resources are available (unanimous)**
- OPTN Bylaw Revisions to Appendix (MPSC) **Primary Goal 4- POC recommends approval with evidence gathering status (unanimous)**
- Reduce Pediatric Liver Waiting List Mortality (Pediatric Committee) **Primary Goal 3 – POC recommends approval with on hold status until resources are available (unanimous)**

6. **Clarifying the OPTN Strategic Goals**

Given that the OPTN strategic plan and its five goals provide the basis for the POC’s review of committee projects and public comment proposals, Board leadership has expressed interest in working with the POC to further refine the working definitions of the goals. In the past the OPTN/UNOS has established some working definitions that we’ve used to gain some consistency in reviewing and assigning projects, and we’ll consider these as part of the discussion. These are the working definitions that the POC used in the discussion:

**Goal 1: Increase the number of transplants**

- This is about increasing the overall size of the pie; not just increasing the number of transplants for a specific population
- Utilizing more organs or finding more donors (deceased or living) increases the number of transplants
- If the gain in outcomes (goal 3) in so large that it might reduce the need for a second transplant, then it could be a goal 1 project
- Reducing discards generally increases the number of transplants
- Ensure that performance metrics for transplant centers and OPOs are aligned and promote increasing the number of effective transplants
- Measure transplant centers’ ability to transplant waitlisted candidates
- Improve transplant program metrics to remove disincentives for transplanting marginal organs
- Improve OPO metrics to remove disincentives for pursuing single-organ donor
- Increase community participation in, and transplants arranged through, OPTN KPD program
- Minimize financial disincentives and remove other barriers to living donation
- Use data to improve the chance of timely offers of organs to centers and candidates most likely to accept
• Develop decision analytics and support tools to guide OPOs and transplant centers
• Conduct follow-up research to deceased donor potential study to assist OPOs in identifying and recovering underutilized categories of donors
• Identify best practices for donor medical management and share with donor hospitals
• Share OPO best practices for maximizing organ utilization and minimizing organ discard rates
• Increase the number of DCD donors

Goal 2: Provide equity in access to transplants
• If you’re only shifting the relative size of the pie pieces, you’re in Goal 2 (increasing equity in access to transplants)
• Access and equity can mean lots of different things: geographical access, access by different types of patients, expanded access for membership, etc.
• Changing allocation rules (without increasing which organs get used) is usually access if it is to help a population gain access to the waiting list. However, it can also be outcomes if it is to better match the organ to the proper recipient (ex. HLA or life year proposals)
• If granting a patient population better access to the waiting list will get them better outcomes, this is probably still an access project. Any patient that gets better access will also have better outcomes compared to not getting an organ offer
• Reduce geographic disparity in access to transplantation of livers and other organs
• Examine the effectiveness of current DSA boundaries and consider developing new methods of distribution
• Establish clearer rules for allocation of multiple organs to a single candidate, especially liver-kidney candidates
• Examine ethical issues in retransplantation when a shortage exists
• Increase the referral of all patients who have a high likelihood of transplant benefit to transplant centers without regard to patient demographics or geography
• Define other measures of equity to examine system performance

Goal 3: Improve waitlisted patient, living donor, and transplant recipient outcomes
• Outcomes and safety are intertwined. In some ways, it is easiest to think of them as a temporal difference. Safety is avoiding negative events; you’ll see the impact of these events in the short term. (Ex. ABO verifications, organ transportation issues, etc.) Outcomes is more about the long-term health/condition of the patient. (Ex. getting the right team in place, LD follow-up data collection, etc.)
• Annual updates to the HLA equivalency table updates are outcomes projects
• Define alternative measures of positive patient outcomes other than one-year survival
• Provide tools to promote self-assessment and improvement by members
• Examine practices to allocate organs in a way that promotes increased transplant benefit across the population
• Promote research on long term (>2 years) living donor outcomes
• Develop and distribute educational materials to assist primary care providers on best practices for partnering with the transplant center in the ongoing care of transplant recipients
• Improve transplant patient literacy in order to facilitate self-management post-transplant
Goal 4: Promote living donor and transplant recipient safety

- Membership requirement proposals are typically safety proposals. (Goal 4) The requirements are there to help safe guard that patients are being treated by trained and experienced clinicians
- While increased safety might make some people more likely to donate, that typically isn’t the primary goal of the project. So those are usually Goal 4 projects. That said, if the focus of a project were to educate people about the high level of safety in the system, then that might be a better argument for a goal 1 project. (Ex. DTAC guidance on effective methods for discussing risk)
- Increase opportunities for members to exchange best practices and responses to near-misses and sentinel events; provide sample forms and other learning tools
- Facilitate more information sharing among members through "safe-harbor" policies
- Share best practices in developing robust quality programs
- Deploy technological tools that improve labelling, tracking, and check-in of organs
- Facilitate improved communication between OPOs and transplant centers
- Implement the HOPE Act while protecting the safety of patients and transplant professionals
- Expand learning opportunities for disease transmission of rare donor derived diseases

Goal 5: Promote the efficient management of the OPTN

- General operational and governance proposals (committee terms, policy development, etc.)
- If you are clarifying a section, you’re probably in goal 5. But think about the underlying proposal. If the underlying proposal that you’re clarifying is a goal 2 project, then the primary goal for the clarifications could also be goal 2
- Align committee proposals to strategic planning goals
- Consider financial impact to OPTN members as part of the policy development process
- Align OPTN requirements with CMS and other standard-setting bodies
- Employ user-friendly technologies to collect data quickly and accurately, and supplement member-submitted data by integrating other data sources
- Create a stronger connections between committees and board
- Consider reducing the number of standing committees
- Identify financial standards and best practices in donation and transplantation
- Partner with other organizations in donation and transplant to minimize duplication of efforts

In discussing these definitions and examples, POC members commented that:

Goal 1: Increase the number of transplants. This one is pretty clear. We’ve struggled to come up with Goal 1 projects, but the goal itself is pretty clear. This remains our number 1 goal.

Goal 2: Provide equity in access. Can mean a lot of things: geographical access, changing allocation rules to help a certain population gain access, and access for different types of patients. If a patient population has more access to transplants they will likely have better outcomes, but that is still an access project and not an outcomes (Goal 3) project. It would be helpful in regards to informed consent projects to have some examples under goal 2 of the types of informed consent projects that increase equity in access. For example, when you have informed consent to liver candidates that live
donation is an option, you’re increasing access. You’re making a patient aware, who might not otherwise be, and increasing access.

Goal 3: What constitutes outcomes (3) and what constitutes safety (4)? Outcomes is more long-term and safety more immediate. Why would we limit the “improve transplant patient literacy” to just post-transplant? This is important along the entire process and can help improve outcomes. Also, promote donor organ experimentation, such as EVLP. Those sorts of projects could improve outcomes. This cuts across all the organ types as well. These sorts or projects could fall under different goals: if you’re increasing use of EVLP to transplant more lungs, that’s a goal 1. We struggle to find projects for goal 3. What defines long term? There is no real answer, what we’ve thought about is more like the immediacy of the impact. Maybe put some wording in to allow for patient advocacy groups to contribute patient outcomes. All of these goals are very patient-centric. The time thing has always been problematic with goal three and four. I’m wondering if there would be a more fruitful way to define these? It might be better if there was more guidance to both of these goals. Maybe there is some literature out there regarding timing for clinical outcomes versus patient safety issues?

Goal 4: Goals 3 and 4 are the ones that we struggle with the most. We’ve had a lot of discussions around “could we tweak this goal 4 to be a goal 3?” We want to make sure we’re staying in the guard rails and not gaming the system. That’s why these definitions are important. These definitions should be shared with your committee leadership when discussing new project ideas so that you get them in the correct goal.

Goal 4 is shorter term and more immediate. Also includes the concept of public trust. If there’s better safety on the living donor side, more people would donate, so does that become a goal 1? Best practices and sharing or “near misses” is an important goal 4.

Why is HOPE act under safety? I understand why that is under safety for professionals, but it is increasing the number of transplants. So how did that get under safety (goal 4)? The policy director reported that the HOPE act project has now been re-categorized as Goal 1 because it is increasing transplants.

Goal 5: Efficiency. This is also pretty clear. This was well defined and no questions were raised about this.

7. Data Advisory Committee (DAC) Request for Input

The DAC liaison, Liz Robbins, led a discussion to collect feedback from POC members about the DAC’s role in policy development. She outlined the goals of the discussion as:

- Review DAC’s proposed role in OPTN policy development process
- Provide feedback regarding whether DAC’s role will provide value to POC during public comment decision-making
- Provide feedback regarding when DAC’s role will provide value

After the presentation, POC members contributed these comments:

- A question came from one committee member: I don’t see a box which I thought I would, which is the analysis during the post-implementation review. Ms. Robbins agreed that that would be helpful, and she thinks that’s an important discussion to have. However, she noted that she thinks that is a separate project.
- The process could also be used to evaluate data we already collect. DAC has not really ironed out the process of once it’s collected.
- Isn’t the pre-implementation box redundant? Ms. Robbins agreed that the standard should be the same for post and pre-implementation review.
• I think if they were going to give a formal approval before it came to us, the important question is what is the timing for this?
• How often would you be doing this review process? If the review happens during the evidence gathering phase, it would already be included during the evidence gathering process. She doesn’t think the DAC involvement during this phase would add time and the data elements they propose would be surprising. That’s one of the questions: would you rather do this during the evidence gathering? Standard practice that a DAC member would be involved in the pieces of the proposal that would involve data collection.
• So this sounds very project based. My thoughts would be to review all the data that’s being collected on a regular basis. Policy director noted that this is done from time-to-time, a review of all the data that’s being collected. Should we do that on a regular basis and if so, when? Right now we don’t have that built into the process, and it can take a lot of resources as far as staff goes. This is more about before we put additional data collection burden on members, we take a good look at that.
• DAC needs to be involved at the earliest possible time. DAC needs to be involved in the consideration to ensure that resources are available early on.
• Question: Several proposals we’ve looked at and the comment talked about need more data or more data collection is needed. I’m not sure if it’s a formal approval or if we just need one member to look at if there’s additional data that needs to be collected?
• Question about the last line: Before requiring transplant member to submit more data first see if the member has data already available that is similar and would be more efficient. Add to the review process: are we doing this consistently with the way they already do things and if not, do we have a really good reason for making them do it differently. Also, CMS and OPTN should be in sync.
• Can you explain the hierarchy of the governmental process? We have CMS, and they’re under HRSA, right. The HRSA rep corrected him that CMS is under HHS. Isn’t it logical that we would all have the same rules since they all report to the same boss? Why can’t we do that? Why is it allowed to have two separate rules for the same governing entity? HRSA rep further clarified that the OPTN is not a government agency, rather this is a federal contract. The POC chair admitted that this is “the elephant in the room.” Policy director James Alcorn provided a brief explanation of why OPTN and CMS are sometimes not in sync. Most important, he emphasized that we do not want to create additional work for the member if it’s not completely necessary.

Ms. Robbins finally summarized the POC input as follows:

1. Add a line to the standard of review, something about avoiding duplication or ensuring consistency with CMS and current member data collection.
2. DAC does not need to have its own public comment approval step but should be involved during evidence gathering. This would however be a part of the final checklist of items that must be completed that the POC would look for before public comment approval. Sponsoring committee would have to show the POC that they’ve consulted with the DAC on the proposal.
3. Input from DAC during evidence gathering will add value to the review process.
4. Let’s imagine there are staff resources available, but there is a problem where a sponsoring committee (like for Liver Redistricting) just realized that they really needed additional data. Would you think DAC should sponsor a data-heavy proposal like that instead of the normal sponsoring committee? Or do you think DAC should
only be advisory and not sponsor a proposal (like the Liver example)? The POC agreed that there may be certain situations where the DAC might sponsor a proposal, just as in the case that POC doesn’t usually sponsor proposals, but we are sometimes called upon to do so.

The whole idea of sponsorship: I do think having the specific committee being very involved would be very important. I think the DAC should be a key member but not all by themselves.

I would think to sponsor that DAC would need representation from the committee.

Final comment: Add to the check list: did the committee research available literature and publications on existing models and data available? Could that be part of the initial project review that they’ve done this?

8. Committee Brainstorming on Volunteer Engagement Strategies

Previously, POC discussed how to measure participation and engagement in order to remove disengaged members. At this meeting the POC discussed another important angle of working with volunteers, particularly the important task of identifying committee members and grooming volunteers for leadership roles. They specifically discussed the following:

- How do we identify the appropriate people for committees, taking into consideration the needs of the community and ensuring equity and inclusiveness?
- Where should we be looking for our future leaders?
- How do we groom new volunteers for leadership positions and help them grow as leaders throughout the entire continuum of OPTN/UNOS participation, from committee service to Board leadership?

Comments from the committee included:

- Question about who will be the representative to bring forward the special things we identify today? What is the forum? Policy director answered that these recommendations to go to the Board.
- Operationally, liaisons work with the chair and vice chair to build committee rosters.
- How do we coordinate the efforts of the regions? They have different models right now and it’s not uniform how it’s done. Staff talks to leadership and identifies the needed positions and the regional administrators are informed about what is needed on a committee and this is communicated for each region.
- It’s a big challenge to meet your goals, the region goals, and an individual hospital or other member’s goals. You don’t want to punish those that have been truly committed and tried and true reps because you want to get new blood in. You struggle with those who have a lot of committee experience and the need to get some new people in with no experience. It’s really really tough to meet the demands of everyone in the region. I fear there is a stigma of being a repeat person on a committee.
- It strikes me that there is not a lot of emphasis on the work groups and subgroups and looking at those folks for level of engagement and skill set. That’s a good resource for possible Board members. Work groups can bring in additional expertise and new blood and are often overlooked as a possible resource.
- Echo Jennifer’s point of opening up subcommittees to those not on the committee to bring in new blood. Kind of a field test, if you will. They decided if they’re really engaged and interested and if they do good work they can get promoted to the committee.
• It’s sometimes difficult to fulfill all the requirements if you’re too prescriptive about all the requirements, particularly for a small field like pancreas, you box yourself into a corner. Need to be flexible.
• Quick math shows that there are 48 volunteers that are considered minorities and 18 of those are on MAC. So really only 30, so I think we should really work on improving that.
• Idea: on the website highlight what the requirements are and what type of people we’re looking for and allow people to enter their names as possible candidates after they’ve reviewed all of these requirements. And report on what their expertise is and other special skills they may have.
• Suggestion to as people are rotating off ask them for recommendations for new people to take their place. Current committee members and those rolling off are often not asked for their recommendations and they should be.
• Database of potential candidates needs to be created. (We currently have a database of former and current committee members.)
• Are you looking for certain qualities…. Should we as Chairs and Vice Chairs keep an eye out for certain qualities or expertise in members so we can make recommendations? There’s an opportunity for improvement in how we document this.
• Maybe a transplant fellowship program… current fellows in training could have an elective 2-week OPTN training to educate new doctors. Because they have chosen to practice transplantation in some form.
• Nominations and tracking them. I hear that the younger people that they try and never get a chance to be on a committee. Do you track that so you can give those people who keep trying and never get on?
• Not everyone wants to be on a committee. Some people do not have the interest, talent, or support from their institutions to be on a committee. We have to be mindful of that. Is there another way or opportunity for those who do not get the support from their institutions to serve? (Especially on the patient side?)
• Question: When you send out the regional requests for application, how do they get that notice? Who does it really get sent to? How do we determine who that is sent to?
• Need to tap donor families more. And living donors. What are avenues in which we can do that? Currently we can look at the nominations for the donor memorial award and also for UNOS ambassador program participants.
• Need to recruit more women on committees and it’s good we’re focusing on that and diversity in general.
• Other society meetings and conferences would be a good way to reach out to potential committee and board members.
• Transplant games: pretty patient-centric but a lot of people very passionate about transplant there.
• OPOs have volunteer networks: tap those. What about social media? How do you work within those to get volunteers and committee members?

9. **Update on the Fiscal Impact Project**

Policy Director James Alcorn presented an update on the Fiscal Impact Project for Emily Ward, Policy Analyst, who was out sick. He provided an executive summary of the project, including the goal of the project and the major milestones:
• The Goal: Enable the Board of Directors to consider high level direct financial implications to members
• Developed process for gathering and reporting fiscal information
• Based on member and staff input
• Draft proposal presented at the June 2016 Board meeting
• Pilot for proposals will be implemented during Fall 2016 public comment cycle

The fiscal impact will provide the following information for the Board’s review:

• One impact estimate per proposal
• Impact to UNOS, OPO, Transplant Centers, Labs
• Includes implementation and ongoing costs
• Includes staff analysis and complexity notes
• Charts and narratives – easy for stakeholder review

Committee members commented that this information would be helpful to have when we analyze the proposals for public comment. James explained how the public comment cycle and process would need to be changed to enable that to happen and how difficult that would be to get that analysis before public comment.

How do we know if our projections are even close to the mark? What kind of review of this will we do to see if we are making good, accurate predictions of cost? We don’t want the cost to impact policy. James agreed that we need some sort of follow up to see if we’re making good estimates.

It’s tough to determine a cost and it’s more than that, it’s also cost/benefit. It’s difficult to know the cost until you know the solution to the problem, which you do not know at project approval a lot of the time.

The numbers for the OPO side are off. Take a look at those numbers, since there are no OPOS that do greater than 600 and only a few do more than 350. That’s not the right metric for OPOs. James said he would take a look at that…

The way they divided small, medium and large for all the members may not be the way to do it. I think you should re-evaluate all those groups. For histo labs that’s not really the right metric to use.

10. Spring Meeting Dates

The committee discussed possible spring meeting dates but could not agree on the best day to hold the in-person Chicago meeting. Also, new Vice Chairs who attended orientation felt it would be valuable for new Vice Chairs to receive the training before they join the committee on July 1 so staff is going to look into holding the orientation before the spring in-person meeting.

Upcoming Meetings

• October 13, 2016, Conference Call, 12-1 p.m. ET
• November 10, 2016, Conference Call, 4-5 p.m. ET
• December 15, 2016, Conference Call, 12-1 p.m. ET
• January 18, 2017, Conference Call, 2 pm-3:00 p.m. EST