OPTN Policy Oversight Committee
Meeting Summary
February 9, 2022
Conference Call

Nicole Turgeon, MD, FACS, Chair
Jennifer Prinz, RN, BSN, MPH, CPTC, Vice Chair

**Introduction**

The Policy Oversight Committee met via Microsoft Teams teleconference on 02/09/2022 to discuss the following agenda items:

1. Project Resources Planning
2. New Projects Review
1. Project Benefit Scoring

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

**1. Project Resources Planning**

UNOS Staff presented on project resources planning. This presentation began with a recap of previous Policy Oversight Committee (POC) discussions, in that the programming complexity and implementation impact of policy changes has increased over time, the available resources have remained the same for some time, and that there appears to be a greater need than available hours, especially with strategic policy priorities.

Staff presented on the technical implementation hour ranges for different projects. Enterprise projects are around 8,400 hours on average, with an example being the proposal to *Establish Continuous Distribution of Lungs*. Very large projects are around 4,100 hours on average, with an example being the proposal to *Modify Data Submission Policies*. Large projects are around 1,710 hours on average, with an example being the proposal for *Data Collection to Align with US Public Health Service Guideline 2020*. Medium projects are around 800 hours on average, with an example being the proposal for *Updating Alcohol-Related Diagnoses and Ongoing Review of the National Liver Review Board (NLRB)*. Staff also clarified that while there are also small and very small projects, they do not have the same impact to the technical implementation budget, so the focus for the discussion would be the larger projects.

Staff presented on the current OPTN technical implementation budget with 15,000 hours available, and the number and size of projects this could contain. The current budget could not contain 2 enterprise projects within a single board cycle. This could almost fit 1 enterprise, 1 very large, and 2 large projects. Staff explained that the maximum number of projects with a non-small technical implementation component in a given cycle based on average sizes would be seven, with one enterprise, two large, and four medium projects. Staff displayed other possible combinations of enterprise, very large, large, and medium projects, and emphasized that many of the upcoming projects are in the large, very large, or enterprise range. Staff then explained that the focus of the presentation will be on the larger projects where POC has already identified priorities and where there are clearly identified budget constraints.

Staff introduced the goal of the meeting as to nail down the policy priorities to determine the size of the gap between implementation needs and currently available resources. Staff explained that the POC members are best at identifying the necessary projects and components that the OPTN needs to

prioritize, and that staff will take that list and determine the resources needed for the work. To do this, the presentation focused on enterprise projects known to be policy development committee priorities to complete within the next 5 years, and smaller projects known to be policy development committee priorities within the next two years. This was since these larger, enterprise-level projects often require significantly more time to development and are known farther in advance, just due to their large scope. Most other projects are developed within 1-2 years, and so we are unlikely to be able to accurately predict projects further out due to their shorter lead time. Staff emphasized that this review was not intended to be a project approval, sequencing, or prioritization, but intended to develop the necessary budget. After POC provides feedback on work that needs to occur, staff will provide the number of technical implementation hours that work would take so that POC is able to develop a request for the budget they believe is necessary to complete OPTN work.

Staff then presented on the known enterprise projects that are OPTN or policy development committee priorities to complete within the next five years, starting at the December 2022 Board Cycle. Staff mentioned that the Strategic Plan and Strategic Policy Priority projects have already been presented to the community and Board. Strategic Policy Priority projects included five continuous distribution projects, three offer efficiency projects, and two Multi-Organ Transplantation projects. Staff emphasized that if the budget remained at the current level, the presented projects would take all of the enterprise-level project spaces for the next five years, with one of these projects per public comment/Board cycle. The Committee Chair then framed the conversation, explaining that with all of the projects we're projecting to be well above our current technical implementation budget, and that the ask to the Committee is really whether or not this is a temporary increase in work due to Continuous Distribution projects or whether this would need to be a longer-term increase in the budget. She then explained that after the POC sees all of these projects in the presentation, the question will be whether these need to move forward and if they're priorities, and if they are the POC will work with staff to determine what a reasonable request is for the Finance Committee based on anticipated work. She explained that POC members need to think about whether any of these projects are less of a priority and don't need to move forward within the given time frame.

Staff presented that there are also five contract-related enterprise data collection projects, and eight enterprise projects that are policy development committee priorities. This totaled 23 enterprise level projects known with an ideal completion date within the next five years.

Staff then presented that there are three very large projects anticipated within the next two years, two of which are strategic policy priorities and one of which is not. In addition, there are 10 large projects, three of which are strategic policy priorities, and six medium projects with a goal completion date within the next two years.

Staff then asked the committee to consider if these projects are all necessary to move forward to drive the change needed for the OPTN, and that staff would take these recommendations to determine the technical implementation hours needed for POC to request a change to the OPTN budget from the Finance Committee. The UNOS Executive Director reminded the committee that POC also needs to provide input on how large of a scope a project should have, and that POC does not have to agree to the proposed scope or size of the project and can ask the sponsoring committee to re-evaluate the project. He then used the example of data collection projects, explaining that they can often be large in scope, and that the POC needs to be able to limit the scope of projects if appropriate and determine the resources the projects will be able to utilize. He also mentioned that the goal of this review was not to fund all ideas and wishes of every committee. The Committee chair responded that in order to be responsible with resources, the POC will be working on their project benefit evaluation to better assess projects and requiring committees to better define their projects. In addition, the POC will require

systematic review if there are changes in project scope.  She also mentioned that the goal of the POC was not to hold back necessary work, but to properly assess that the work moving forward is appropriate and request additional resources as needed.

A committee member stated that there absolutely needs to be an increase in the technical implementation budget, but that he was unsure of how the numbers would add up. He also said that the POC can approve a certain number of hours per project, and committees can come back if they exceed that initial approved scope and request and justify their need for additional hours. He also mentioned that the committees haven't historically understood the budget or been approved for specific hours in the part, and that ensuring committees understand and work within the budget and their approved scope would decrease frustration from delayed implementations. The Chair mentioned that in the past the POC hasn't been as transparent about the budget and scope just due to a lack of knowledge, and that improving this process will lead us in that direction and that giving committees an allowed budget for a project with clear expectations on scope will be helpful.

Another committee member mentioned that a lot of the enterprise projects are related to continuous distribution and asked if after a couple of organs move through the implementation will be easier with a developed framework. Staff mentioned that this was a point of internal discussion, and that the IT department is looking to build an iterative and editable system and is working towards that point. Staff then mentioned that with the continuous distribution projects, there are many pieces beyond the allocation framework, and gave the example of kidney continuous distribution also including additional work on multi-organ transplantation and changing the medical urgency criteria.

A committee member asked if kidney and pancreas continuous distribution would be two separate enterprise projects or be combined into one because they tend to work together. Staff explained that those are being evaluated as two separate enterprise projects, because even though they are being planned together, and pancreas would be a slightly smaller size than kidney, they would each be enterprise level by themselves especially with the additional complexity added for the interplay of kidney-pancreas allocation.

The chair recommended that the POC request additional technical implementation hours and asked if any members disagreed with that recommendation. No members expressed disagreement or concern.

Staff clarified that all of the enterprise projects would need to move forward and asked if any members thought that any of the projects did not need to be completed within the next five years. One member asked what the alternatives to moving the projects forward would be. Staff clarified that the request wasn't for project approval, but just whether or not all of the listed projects need to occur within the next five years and be budgeted for.

One member asked if the volume of patients in VCA transplants meant that the VCA continuous distribution could be lower priority, or if it should be more of a priority because the patients are few and far between. The VCA Vice Chair said that the volumes for VCA are small overall, and uterus is increasing the most, especially with deceased donors. She then clarified that the distribution does tend to be broader, since there are more donor-specific restrictions such as bone structure, skin tone, age, and gender. She said that right now VCA isn't even in UNet$^{SM}$, and that there isn't parity with the other organ groups in terms of allocation. The Chair stated that ultimately, the committee did not disagree with projects moving forward as they were reviewed, and that they all do need to move on and be budgeted for.

Next steps:

Staff will take the recommendation from the committee to budget for all of the reviewed projects and determine the resources required. The POC will then develop a request to the Finance Committee to increase the available budget for technical implementation.

**2. New Projects Review**

The Committee reviewed projects submitted for new project approval. This review included overview of the current approved portfolio of work pre-implementation with strategic plan alignment by level of effort, project alignment with strategic policy priorities, and overall project staff resources needed, and the technical implementation hours by Board Cycle for the next two cycles before and with the addition of the new projects.

For individual projects, the committee reviewed the purpose and rationale, the strategic plan goal a project falls within, the key metric and rationale for each project, current committee projects and collaborations for bandwidth, and the committees collaborating on each project.

The discussion points for committee consideration were as follows:

- Is this the right timing for this project in the context of other work?
    - Is it sequenced appropriately?
    - Are there other projects that should come first?
- Does this need to go ahead of or concurrent with any current projects to support their work?
- Is there any additional feedback to improve alignment across projects?


*Ethical Evaluation of Multiple Listing (Ethics Committee)*

The Ethics Committee Vice Chair presented the project to the Policy Oversight Committee. The purpose of the project is to develop a white paper evaluating the ethical implications of permitting patients to be listed at multiple transplant programs. He mentioned that this can advantage higher socioeconomic status patients, and that patients who multiple list can experience up to a 40% advantage on the waiting list and have a quicker deceased donor kidney transplant by an estimated 2.5 years. This project will consider the ethical impact on patients who are able and unable to pursue multiple listing, the resource strain that multiple listing can have on transplant programs, how to best balance equity and autonomy for patients in the context of multiple listing to minimize health inequities, and some ethical tradeoffs have also been identified within utility. He emphasized that the purpose of the white paper is not to encourage the removal of multiple listing, but rather to understand the ethical impact of this practice on the overall system. The rationale for the project is that an ethical analysis is needed to better understand the ethical tradeoffs that occur, both at the patient level and transplant program level, when a patient pursues multiple listing. The strategic plan goal for this project is to increase equity in access to transplants.

The discussion lead was unable to attend the meeting, so staff read the comments sent in ahead of the meeting by other project review members. Staff reported that the comments included support from all group members, agreed that the Ethics Committee was the appropriate group to lead the project, the topic was reasonable and helpful, and that it was most appropriate for this project to occur prior to kidney continuous distribution and multi-organ for kidney transplant. Another member mentioned that there are occasionally HRSA sensitivities towards white papers and asked if the group was aware of any potential sensitivities for this topic before the committee focuses their effort on it. Staff clarified that this project was sent to HRSA ahead of the meeting, with the authority statements and explanation, and that HRSA has not expressed any concerns to staff and do have the ability to speak up on the call as well if they are concerned. A HRSA staff member spoke up and said that she would bring this concern back to

HRSA and follow up if there are any concerns from HRSA. The HRSA Chief of the Organ Transplantation Branch of the Health Systems Bureau mentioned that she will also make sure this is addressed.

A committee member mentioned that one of the purposes of broader distribution is to decrease geographic inequities in access to transplant and may reduce the need for patients to multiple list and asked that the committee think about that when performing this analysis. The Vice Chair responded that the Ethics Committee is aware that the changes to allocation will impact this practice and requested that the member follow up afterwards with additional detail so that the Ethics Committee can ensure to evaluate the concern. A HRSA staff member requested to be included on this follow-up.

Another committee member mentioned that multiple listings in lung transplantation are often due to candidate biological disadvantages, such as sensitization, short stature, or blood type, and that continuous distribution will account for many of these attributes. The member asked that the committee look into what the other reasons for multiple listing are, and the difference between thoracic organs and kidneys. She stated that it appears that often thoracic organ multiple listing is more physiologically based, but that she would appreciate the Ethics Committee examining this. The Ethics Vice Chair mentioned that the discussions have been more kidney focused so far, but that he will bring the point of needing to consider other organs back to the committee and appreciated her input.

*Enhancements to DonorNet Clinical Data Collection (OPO Committee)*

The OPO Vice Chair presented the project to the Policy Oversight Committee. The purpose of this project is to update clinical data reported in DonorNet to better capture information used by transplant hospitals during donor and organ evaluation. The proposed changes include additional information on echocardiograms, medications/fluids, infectious disease testing, and donation after circulatory death (DCD). The strategic plan goal for this project is to increase the number of transplants through an increase in offer efficiency, and the metrics for project evaluation are the use of the new data fields following implementation.

This workgroup prioritized portions of this project, knowing that the technical implementation resources for the December 2022 OPTN Board cycle are limited. Their top priority was DCD data collection (estimated at "very large"), followed by infectious disease testing (estimated at "small"), medications/fluids (estimated at "large"), and the lowest priority was echocardiogram information (estimated at "large"). The 2022 OPTN Board cycle has insufficient technical implementation resources for the project to contain all components as proposed. The OPO Vice Chair mentioned that the infectious disease testing component of the project was initially going to be a very large implementation effort, but after revisions it was a small effort. The POC Chair mentioned that the workgroup did a wonderful job in prioritizing the components of the project, but since the project as a whole would be over the remaining budget for the Board cycle, and that POC will need to consider how to evaluate and approve the project as a whole. One member mentioned that there was more currently slotted on the next cycle than there is capacity to implement, and that if one piece of the project won't be taken it would likely be longer down the road before the OPO committee could take it up. He asked the Chair how members could understand what happens to projects that are pushed off to a future cycle. The Chair said that the POC is going to ask for an increase in the technical implementation budget, and that if there is an increase in available hours it would likely be less of an issue to implement in the future. She also said that the POC can't approve everything knowing that the resources are short.

An SRTR representative asked that the OPO committee and Data Advisory Committees ensure that every data element collected have clear definitions, as the SRTR risk adjusts and risk stratifies everything based on donor and recipient characteristics. He gave an example of different pressor types, dose, and administration type all affecting that the data is well defined and worthwhile collecting. He also

mentioned that ejection fractions are often reported as ranges when echocardiograms are reported, and that for the data to be meaningful the committee will need to clarify if they're asking for the data to be reported as the range, the upper or lower bound, or the median. He also asked if the OPO committee considered adding a systems improvement for the tracking of acceptance/decline patterns and late declines. The OPO Vice Chair responded that the committee wants to ensure that the data fields being collected are meaningful and worthwhile and ensure clarity in the definitions. The SRTR representative mentioned that if there are fields that are less effective, they should be removed and replaced by these data fields so that there isn't an increase in the overall data burden. The OPO Vice Chair mentioned that many of the existing fields are incorporated for a reason, but that they'll evaluate existing data fields. The POC Chair reminded members of the scope of the project review.

The POC Chair then asked the OPO chair about removing the echocardiogram piece of the project, as it was the piece the workgroup had put as their lowest priority. The OPO Vice Chair said that he would like further input from the committee, since if they can only complete three of the portions of the project the infectious disease portion may be less impactful to organ offer evaluation.

The discussion group lead mentioned that the workgroup needs input from the Ad Hoc Disease Transmission Advisory Committee (DTAC) if they continue with the infectious disease portion of the project. He also mentioned that the infectious disease portion of the project affects all organs, and frequently impacts organ acceptance decisions. He mentioned that the other questions from the group included a multi-step implementation, with creating the fields and allowing for manual data entry prior to an automated upload and asked if it would be more feasible. He also re-iterated that the data elements proposed need to be clear and that people need to be appropriately engaged to execute this correctly. The OPO Vice Chair mentioned that the infectious disease testing portion of the project is limited in scope to put in additional date/time/results, and that it would verify that the testing was done within the required timeframe by policy and allow for sequential data entry. He mentioned that this is nice to have but is not removing or limiting critical data for organ acceptance. He also mentioned that the Heart Committee has given input on some of the suggested fields which may be able to reduce the overall data burden for that portion of the project. The SRTR representative mentioned that COVID test results being serial is important to adjust for decline/acceptance patterns and that there isn't the capacity right now. A UNOS staff member clarified that there is already serial capability for COVID testing, and that this is the only infectious disease that currently has serial capability in DonorNet.

The discussion group lead stated that they were in agreement that the timing and sequencing of the project are appropriate. He also mentioned that the infectious disease portion of the project may have some overlap with DTAC efforts and that the OPO committee would need to engage with them.

The POC Chair summarized the sentiment of POC as being in favor of the project as a whole, but that the OPO committee will need to discuss both the infectious disease data elements and their prioritization of different portions of the project. A member stated agreement, and no members disagreed.

One member asked if the project could be approved in pieces so that the OPO committee would be able to keep forward momentum. The POC chair stated that the project would need to be evaluated as a whole.

There were no concerns raised about the purview or legal authority of the OPTN for this project by committee members or attendees.

Next steps:

The Executive Committee will review the POC's recommendations for project approval at their February 18th meeting. The OPO committee will discuss and revise their scope and bring their project back for approval at a future meeting.

3. **Project Benefit Scoring**

The Committee was reminded about the results from their project benefit attribute survey. There was not enough time for discussion of this item, and it will be discussed at an upcoming meeting.

**Upcoming Meetings**

- March 9, 2022, 2 PM EST, Teleconference
- March 28, 2022, 12 PM EDT, Teleconference
- April 11, 2022, 12 PM EDT, Teleconference
- May 2, 2022, 9 AM CDT, Chicago, IL

**Attendance**

- **Committee Members**
    - Alden Doyle
    - Alexandra Glazier
    - Andrew Flescher
    - Emily Perito
    - Jennifer Prinz
    - Jim Kim
    - John Lunz
    - Lara Danziger-Isakov
    - Marie Budev
    - Nahel Elias
    - Natalie Santiago Blackwell
    - Nicole Turgeon
    - Oyedolamu Olaitan
    - PJ Geragthy
    - Sandra Amaral
    - Scott Biggins
    - Sumit Mohan
    - Susan Zylicz
    - Valinda Jones
    - Zoe Steward Lewis
- **HRSA Representatives**
    - Marilyn Levi
    - Shannon Taitt
- **SRTR Staff**
    - Ryutaro Hirose
- **UNOS Staff**
    - Amber Wilk
    - Amelia Devereaux
    - Amy Putnam
    - Betsy Gans
    - Brian Shepard
    - Carrie Caumont
    - Cole Fox
    - Courtney Jett
    - Darren Stewart
    - Elizabeth Miller
    - Eric Messick
    - Isaac Hager
    - James Alcorn
    - Janis Rosenberg
    - Joann White
    - Kaitlin Swanner
    - Kayla Temple
    - Kelley Poff
    - Kimberly Uccellini

- o Krissy Laurie
- o Kristina Hogan
- o Laura Schmitt
- o Lauren Mauk
- o Leah Slife
- o Lindsay Larkin
- o Lloyd Board
- o Matt Cafarella
- o Meghan McDermott
- o Rebecca Brookman
- o Rebecca Murdock
- o Robert Hunter
- o Roger Brown
- o Sally Aungier
- o Sharon Shepherd
- o Susan Tlusty
- o Susie Sprinson
- o Tina Rhoades