

Meeting Summary

OPTN Policy Oversight Committee
Meeting Summary
October 19, 2021
Conference Call

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Introduction

The Policy Oversight Committee (POC) met via Citrix GoToMeeting teleconference on 10/19/2021 to discuss the following agenda items:

- 1. Committee Project Portfolio Management Discussion
- 2. New Project Review
- 3. Biopsy Best Practices Workgroup Update
- 4. Redefine Provisional Yes Update

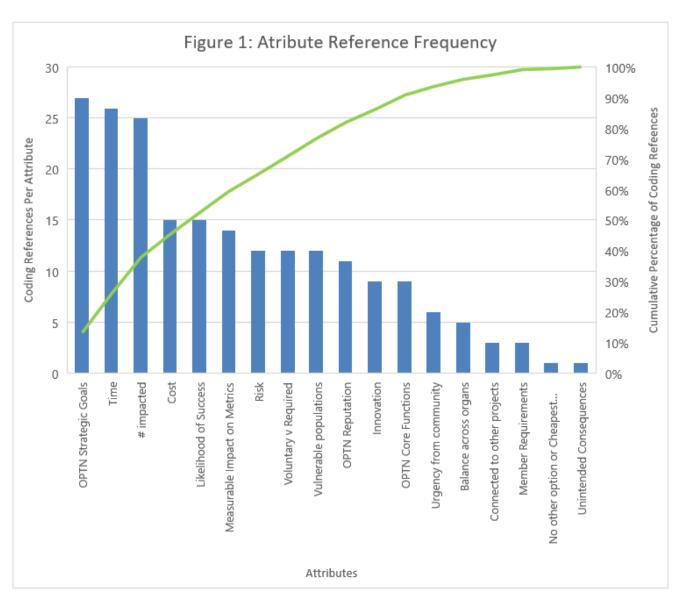
The following is a summary of the Committee's discussions.

1. Committee Project Portfolio Management Discussion

The Committee reviewed the feedback provided by the POC breakout groups and individual interviews related to defining value for a project. The Committee reviewed project benefit framework, refined definitions of specific benefits, and was asked to complete an analytic hierarchy process (AHP) exercise to provide feedback on the appropriate weight and ranking of each potential benefit measure. Those results will be reviewed on an upcoming call.

Data summary:

The Committee was provided a copy of the Portfolio Management Project Value Scores report, providing an overview of the POC and staff's discussion regarding committee project portfolio management with a recent focus on defining the value of each project. It included Figure 1 below, showing the frequency which the most common potential attributes were presented.



Summary of discussion:

The Committee considered how to incorporate evaluation of relative benefit of multiple projects while reviewing projects on a rolling, individual basis. The expectation is that projects will be reviewed in small batches, perhaps once a quarter, and that upcoming projects will also be considered for project management planning purposes. Additionally, there may be times when a project needs to be reconsidered after approval, but the level of development will be taken into account. A Committee member asked how projects that are not approved based on resource availability will be considered – if the Committee will continue to consider them at each successive meeting, or if they will eventually be turned down completely. The projects presented to the POC at each review would be vetted with the sponsoring committees and reflect the feedback from the POC on any past reviews, so that only the projects that are ready to go and top committee priorities would be presented to the POC for consideration, as is done now. The analysis of cost and value might change over time for a project (for instance, solutions tied to technology that is advancing), and the analysis would appropriately be updated in those cases.

The Committee discussed attributes in three categories: not helpful, maybe helpful, and helpful.

Not Helpful

The Committee agreed that whether a project aligned with the core functions of the OPTN was not helpful, since that categorization is primarily used to align work with staff, and all work should align, so it would not be helpful in prioritizing.

The Committee agreed that the time since the problem was identified was not a helpful measure of project benefit, since in some cases a project might have become outdated or resolved in another way in the intervening time. Further, this measure would not tell anything about how important the project is to the community. However, where the time since a project was identified could be helpful is for those projects that have an impact on small or rare populations (i.e.pediatric population). The Committee thought that was better addressed directly, by adding consideration of vulnerable populations. The Committee also considered whether the time since a project was identified could be a question of reputation, if a problem is known for a long time but not addressed but decided that that could be better addressed in a specific reputation measure as well.

Maybe Helpful

The Committee discussed whether a project being identified as a safety project was a helpful measure, and decided that this was not needed as a separate measure, but should be included in the analysis of whether a project addresses the OPTN priorities, since "Promote living donor and transplant recipient safety" is one of the four priorities included in the OPTN strategic plan. It also has the potential to fall under reputation risk, since any project with the goal of reducing the changes of a catastrophic event would also reduce the risk to the reputation of the OPTN.

The Committee considered whether to include data collection as a potentially helpful measure of project benefit. Often, additional data collection is needed to inform future policy development and analysis. Many projects include some data collection as part of the project, so this may not differentiate very well between projects. Some members expressed concern that with previous projects, data collection has been avoided in order to keep costs down or in anticipation of resistance to a potential increase in the data burden. Members of the Committee also discussed whether data collection rose to the level of a measure that should be used to evaluate all projects, or if it was more of an exception. The Committee wanted to focus on the measures that were most helpful overall. These members suggested that if data collection was considered a positive in the evaluation of projects, that would have to be communicated to the committees and the community. The Committee chose to include a data collection element in their AHP exercise and evaluate whether to include it in the final measures based on the results of that exercise. The Committee defined data collection as data collection that assists in developing future efforts.

The Committee chose not to include likelihood of success as a metric for evaluating project benefit because it doesn't directly address the project benefit and can be difficult to predict.

Helpful

The Committee discussed the most helpful definition of the size of the population impacted, considering members, candidates, or percentage of a target population. The Committee considered the value in using a proportion in protecting the more vulnerable and smaller populations, but decided that these were best protected with the separate vulnerable populations measure, and this measure should focus on a number rather than a percentage. The Committee also wanted to focus on patients rather than programs, but believed that certain proposals would only affect programs, and not directly affect patients (like some bylaws proposals). The definition chosen was "The more patients or programs that

are impacted, the greater the value of the project, if all other factors are equal. It also prioritizes patients over programs when necessary."

The Committee discussed the definition of OPTN reputation. This consideration would have the potential to cover unusual, but important, considerations, such as legal risk, identified system limitations, or threats to patient safety. The Committee recognized that not all factors will fit into the scoring system, and there will still be a need to discuss projects and have conversations about the relative merit. The scoring system is just a starting place because not all considerations can be incorporated into a score. Committee members discussed splitting this attribute into two attributes — innovation and public trust (or something similar). The Committee decided to add the attribute of innovation, but not public trust or OPTN reputation. The Committee felt that all projects should be aligned with maintaining the public trust in the system, while acknowledging that sometimes there are projects that rise to a higher urgency at the request of the community. The Committee also discussed that safety concerns would partially be addressed by a public trust measure, but even if the public trust category was dropped, those would still be covered in the OPTN priorities. The Committee chose not to include public trust, and to incorporate trust in the specific project discussion.

The Committee discussed how to approach project dependency. One option is to provide some credit to the initial projects that are necessary for projects that are planned to follow, and the other is to consider all of the included projects together as a single package. A committee member suggested that this measure more appropriately addressed the goal discussed in relation to data collection – that a project may be important because it is the foundation for future work. This idea overlaps with considering when something is a strategic policy priority, since those are often interrelated suites of projects, but may also apply to projects that are not strategic policy priorities. The Committee chose to evaluate each project individually, and include the project benefit attribute in the AHP exercise. The Committee defined project dependency as "projects that serve as part of a project collection that are grouped together (where the projects may be submitted individually or collectively), or dependent upon future work, while they might not have a measurable impact, or be in use for very long, are important in order to achieve transformational changes."

The Committee also considered the time the solution will be in use, whether a solution is likely to be voluntary or required, the measurable impact and impact on vulnerable populations as potentially helpful metrics to include.

Next steps:

The Committee will complete the AHP exercise to prioritize among these attributes..

2. New Project Review

The Committee reviewed one new project, Ongoing Review of National Liver Review Board (NLRB) Policy and Guidance, sponsored by the Liver and Intestinal Organ Transplantation Committee.

Summary of discussion:

The Committee discussed the impact of the fact that the projects approved at the December 2020 Board of Directors meeting being budgeted as 25,000 hours of implementation hours compared to 15,000 hours targeted for each Board meeting. The primary impact of this kind of one-time overage is that it is more likely that not all of the projects will be implemented within the 12 month target time frame following approval. The Committee will continue to improve the visualization of hours allocated, consider showing any overage's impact on future board meeting budgets, while the implementation efforts catch up.

The new project includes improvements identified by rolling review of the exceptions submitted to the NLRB. The Committee agreed that the effort was a good idea, and asked the Liver Committee's Vice Chair if it was possible to separate out the components of the project that would require technical implementation and focus on the aspects that do not require technical implementation. The Liver Committee's Vice Chair responded that while that was possible, it was more efficient to address everything all together, and the Committee agreed. The Committee approved the new project.

Next steps:

The Committee will refer the new project for consideration by the Executive Committee at an upcoming meeting.

3. Biopsy Best Practices Workgroup Update

A representative from the Biopsy Best Practices Workgroup presented the work completed by the Workgroup to date. There are two components to the work that will be circulated for public comment in 2022, minimum donor criteria and a standardized pathology report.

Summary of discussion:

The Committee asked whether there could be a benefit to releasing a guidance document ahead of formal policy changes in order to address the need for this project to develop more quickly. The Committee was reassured by the expectation that the minimum donor criteria will be able to be implemented more quickly than the standardized pathology report due to the fact that it does not include data collection that requires review by the Office of Management and Budget (OMB) prior to implementation. The Committee was supportive of the work to date and the path forward for these projects.

4. Redefine Provisional Yes Update

The Match Run Rules Workgroup Chair presented the work completed by the Workgroup to date, and their planned next steps. The Workgroup proposed a tiered system, with tiers of 1) provisional yes, 2) offer reviewed, and 3) provisional acceptance.

Summary of discussion:

The Committee questioned whether this solved the problems with provisional yes, or was simply superficial changes that wouldn't result in positive changes. The Workgroup Chair assured the Committee that this approach would be more able to be enforced, and have clearer expectations of both the OPO and the transplant program. The Committee also asked about whether there would be a limit on the number of offers, and the Workgroup Chair responded that that would be important to include. The Committee was largely supportive of a broader approach to ensure the Workgroup identified the best possible solution.

Upcoming Meetings

November 10, 2021, 2 PM ET, Teleconference

Attendance

Committee Members

- o Alex Glazier
- Jennifer Prinz
- o Alden Doyle
- o Alejandro Diez
- o Andrew Flescher
- o Emily Perito
- o Garrett Erdle
- o Jim Kim
- o Lara Danziger-Isakov
- o Marie Budev
- Molly McCarthy
- Nahel Elias
- o Natalie Blackwell
- o Nicole Turgeon
- o Oyedolamu Olaitan
- o Rocky Daly
- o Sandy Amaral
- Scott Biggins
- o Sumit Mohan
- Susan Zylicz

• HRSA Representatives

- o Adriana Martinez
- o Jim Bowman
- o Vanessa Arriola

SRTR Staff

o Jon Snyder

UNOS Staff

- o Amber Wilk
- o Brian Shepard
- o Chelsea Haynes
- o Courtney Jett
- o James Alcorn
- o Janis Rosenberg
- Kristina Hogan
- o Laura Cartwright
- o Lindsay Larkin
- o Matt Cafarella
- Matt Prentice
- o Maureen McBride
- o Meghan McDermott
- o Roger Brown
- o Sharon Shepherd
- Susan Tlusty
- Tina Rhoades
- Elizabeth Miller

- o Joann White
- o Kayla Temple