OPTN Executive Committee
Meeting Summary
April 28, 2023
Webex

Jerry McCauley, MD, MPH, FACP, Chair

Introduction

The OPTN Executive Committee met via Cisco Webex Meetings teleconference on 04/28/2023 to discuss the following agenda items:

1. IT Implementation Timeline Updates
2. Clarification of Diagnostic Criteria in NLRB Guidance for Hepatocellular Carcinoma (HCC)*
3. New Projects from the Policy Oversight Committee (POC)*
    a. Collect Donor Continuous Renal Replacement Therapy (CRRT), Dialysis, and ECMO Data (Operations & Safety)
    b. Living Donor Granular Data Collection (Living Donor)
    c. Collect Living Donor Candidate and Donation Decision Data (Living Donor)
    d. Required Reporting of Patient Safety Events (Membership & Professional Standards)
    e. Revise Donor and Recipient Histocompatibility Forms (Histocompatibility)
    f. Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates (Histocompatibility)

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

1. IT Implementation Timeline Updates

Mr. Michael Ghaffari, Senior Director of Technology Development, and Mr. Michael Ferguson, IT Portfolio Manager, presented an update on the IT implementation timeline. The committee received updates on project proposals going before the Board in June 2023 along with the proposed timeline of each project, the changes in delivery timeframes, and a progress update on the capacity expansion requested by the Policy Oversight Committee (POC).

Mr. Ferguson presented an updated roadmap on project and resource allocation as of the June 2023 Board meeting. The roadmap detailed the projects that software engineering is actively working on, which teams are implementing which projects, and the expected timeframe of each. Changes to the delivery timeframes included the change in the OMB data collection package moving from May 14 to September 14 of this year. The change in timeline is due to the time needed for EMR vendors to prepare for these changes within their systems. Changes that were in the policy to Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation have moved from June 2023 to September 2023. The committee was shown a roadmap of how the project factors into the other work the software engineering teams are currently working on and how this change in implementation could alter other projects.

The committee heard an update on the expansion of IT implementation hours and the capacity expansion that was requested from the POC. The capacity expansion plan is to increase the policy technology budget from 15,000 programming hours to 30,000 programming hours by June 2024.

Summary of discussion:

A committee member asked how close the team was to operating at maximum capacity, to which Mr. Ferguson explained that teams are currently operating at their maximum capacity. Another committee member asked how much of these delays are due to the OMB approval process versus an integrator impact. Mr. Ferguson explained that the delay is unrelated to the OMB approval process, but instead has to do with the integrators side of operations.

A representative from HRSA asked about the relationship between continuous distribution and the capacity expansion on IT implementation hours. They asked that since there has been a predicted delay of six months on kidney-pancreas continuous distribution, how would this be factored into the roadmap and will these implementation hours be reallocated. Mr. Roger Brown, Director of Policy, explained the reason for the delay and explained that the kidney-pancreas team will submit their updated timeline and project proposal to the POC and Executive Committee in May, and then the roadmap will be updated accordingly. A committee member commented that it is important to prepare the proposal in good condition for the sake of patients and to not rush a proposal for public comment.

2. Clarification of Diagnostic Criteria in NLRB Guidance for Hepatocellular Carcinoma (HCC)

Dr. James Trotter, Member of the Liver and Intestinal Organ Transplantation Committee, presented the Clarification on Diagnostic Criteria in NLRB Guidance for Hepatocellular Carcinoma (HCC) proposal on behalf of the committee. The purpose of the clarification is to align the diagnostic criteria in HCC guidance. Currently, diagnostic criteria for classifying HCC, as of June 2022, is different than diagnostic criteria for classifying HCC in existing guidance. The misalignment was brought to the attention of the committee, and this clarification is an effort to align with the current mode of diagnosing HCC. The Liver and Intestinal Organ Transplantation Committee is looking to align the policy with current clinical practices.

Dr. Trotter shared where the changes in policy would take effect and how the language would better align within the guidance document. The Liver and Intestinal Organs Transplantation Committee's proposal for consideration was to update the diagnostic criteria in existing guidance to align with the June 2022 diagnostic criteria.

Summary of discussion:

There were no questions or comments from the committee.

Vote:

By a vote of 7 approve, 0 decline, and 0 abstentions.

> **RESOLVED**, that the changes to the guidance document *Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exceptions for Hepatocellular Carcinoma (HCC)*, as set forth in the materials distributed on April 26, 2023, are hereby approved, effective April 28, 2023.

3. New Projects from the Policy Oversight Committee (POC)*

Dr. Nicole Turgeon, Chair of the Policy Oversight Committee (POC), presented a new initiative from the POC to bundle new policy projects to bring to the Executive Committee for their review. Dr. Turgeon also presented six new projects from the POC.

Dr. Turgeon explained that the new bundling initiative from the committee aims to review more projects at fewer meetings to increase efficiency and prioritize projects within the system. The POC was supportive of the changes and felt it maximized their time and efficiency while promoting thoughtful dialogue about all the discussed projects. However, the POC also agreed that the bundled review of

projects should not delay any important projects from being discussed and that a staggered approach may be necessary in the short term with the pilot. Dr. Turgeon presented the metrics of the six new projects the committee bundled to present today and highlighted the relevant details for each project prior to each project vote.

The new projects from the POC were:

- Collect Donor Continuous Renal Replacement Therapy (CRRT), dialysis, and ECMO data from the Operations and Safety Committee
- Living Donor Granular Data Collection from the Living Donor Committee
- Collect Living Donor Candidate and Donation Decision Data from the Living Donor Committee
- Required Reporting of Patient Safety Events from the Membership and Professional Standards Committee
- Revise Donor and Recipient Histocompatibility Forms from the Histocompatibility Committee
- Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates from the Histocompatibility Committee.

The POC gave a benefit score to each project on measurability, vulnerable populations, population size, percentage of the population, and the policy priority. The committee also looked at the overall benefit score of each project when all portions of the score were combined.

Summary of discussion:

A committee member asked if there were any potential negative consequences to bundling. Dr. Turgeon stated that the POC did not find any overwhelming downsides to the work. She noted that one potential downside would be slowing down the committee's work if they were waiting for the POC to meet and discuss the project. However, the committee agreed that if any projects were being delayed for this reason, they could present the project sooner rather than waiting to bundle it.

Collect Donor Continuous Renal Replacement Therapy (CRRT), Dialysis, and ECMO Data (Operations & Safety)

Dr. Turgeon explained that the purpose of the project from the Operations and Safety Committee (OSC) to Collect Donor CRRT, Dialysis, and ECMO Data is to collect data on donor support therapies to promote the efficient review of organ offers from donors on CRRT or ECMO. The goal is for the data to provide granular information to include in the ongoing offer filters effort and to standardize the reporting of these data. The project aligns with the strategic plan to increase the number of transplants. The proposal stemmed from an offer filters workgroup request and was also a general request from members of the OSC for standardization. There is currently no other data source for this information, so this project will require additional data collection in the OPTN Donor Data and Matching System.

Dr. Turgeon shared the other projects the OSC is currently working on, the other committees that would be collaborating on the project, and the technical implementation hours the project would need. She also shared that there was unanimous support of the project from the POC, and they identified the project as an important priority for the OPTN in terms of progression. The project scored highest in benefit scoring for policy priority and measurability metrics.

Summary of Discussion:

A committee member asked if there would be any extra work required of centers and Dr. Turgeon explained that the change would be as simple as OPOs clicking a button.

Vote:

The Executive Committee approved the initiation of the new project to Collect Donor Continuous Renal Replacement Therapy (CRRT), Dialysis, and ECMO Data from the Operations and Safety Committee.

Living Donor Granular Data Collection (Living Donor Committee)

Dr. Turgeon presented a new project from the Living Donor Committee to update Living Donor Feedback, Living Donor Registration, and Living Donor Follow-up data instruments. The updated data collection would help ensure accurate data collection on living donors, improve analyses to inform living donation decision-making, and improve evidence-based policy making. Additional modifications to OPTN living donor data collection instruments would include restricting sections to help ease data entry and provide more clarity, as well as making any updates to data definitions to help with documentation.

Dr. Turgeon explained that this project is one of two new projects from the Living Donor Committee, and the committee is currently collaborating on five other projects across the OPTN. The Data Advisory Committee (DAC) is collaborating on this project with the Living Donor Committee. During the POC's review, the committee unanimously approved the proposal and had it score highest on the benefit score in vulnerable populations. Some committee members were initially surprised how high the Living Donor projects scored but understood the importance of the effort.

Summary of Discussion:

A committee member commented that although they support the collection of granular data, this project appears to be a total change in workflow. That although the Living Donor Committee plans to collaborate with the DAC on the project, it would be beneficial to also collaborate with the Transplant Administrators Committee (TAC) early in the process so the Living Donor Committee can hear directly from administrators how important this data would be to their work. If administrators are brought on earlier in the process, it might make the overall adoption of the policy smoother. Dr. Turgeon concurred that this was an excellent idea and would take the feedback to the Living Donor Committee.

A representative from HRSA commented that the Living Donor Collective is an SRTR activity and if this initiative from the SRTR is successful in collecting long-term, living donor health information, then the this could reduce the data collected by the OPTN.

Vote:

The Executive Committee approved the initiation of the new project on Living Donor Granular Data Collection from the Living Donor Committee.

Collect Living Donor Candidate and Donation Decision Data (Living Donor Committee)

Dr. Turgeon presented the concept paper from the Living Donor Committee to Collect Living Donor Candidate and Donation Decision Data to improve data on long-term outcomes of living donation through a collaboration between the SRTR Living Donor Collective and the OPTN. Collecting living donor candidate data will allow for data collection on appropriate comparator groups to analyze the risks and benefits attributable to live organ donation. Collecting donation decision data will allow for analysis regarding equitable access to living donation and reasons for not donating. The upstream data collection by the OPTN will help support the SRTR's Living Donor Collective as a national living donor registry. With the OPTN collecting front end data, the SRTR's Living Donor Collective can collect downstream data and assess long-term outcomes of living donors and living donor candidates. The concept paper aligns with the strategic plan to promote living donation and transplant recipient safety.

This project is one of two new project proposals from the Living Donor Committee and the committee is also currently collaborating on five other OPTN projects. The Data Advisory Committee (DAC) is collaborating on this project with the Living Donor Committee. The POC unanimously approved the new

project to the Executive Committee and were supportive of the effort to pursue efficiencies of collaboration between the OPTN and SRTR.

Summary of Discussion:

A committee member commented that they wouldn't be surprised if there is push back on this project from the community, but they think this is important work that needs to be done, regardless of the extra work it may require. There has been a need for a living donor database for a longtime, this database helps show living donors that we care about their decision-making consent and their long-term outcomes.

Vote:

Following the April 28th meeting, the Executive Committee approved the initiation of the new project to Collect Living Donor Candidate and Donation Decision Data from the Policy Oversight Committee. The vote was conducted via email due to a loss of quorum.

Required Reporting of Patient Safety Events (Membership & Professional Standards Committee)

Dr. Turgeon presented the project to Require Reporting of Patient Safety Events from the Membership & Professional Standards Committee (MPSC). The proposal aims to update Policy 18.5 to include certain types of safety events within a specific timeframe and to include additional concerning patient safety events that members would be required to report. This project would update the Improving Patient Safety Portal instructions with an updated list of safety events members are required to report. The project aligns with the strategic plan to promote living donation and transplant recipient safety.

Dr. Turgeon explained that the MPSC is collaborating on three other committees across the OPTN and plans to collaborate on this project with the OSC and Living Donor Committees. The technical implementation of this project would be minimal, with an estimate of about 35 hours. The POC unanimously approved recommending the project to the Executive Committee, and the project scored highest in measurability and the population the policy would impact. The POC agreed that the project was an important safety and efficiency effort.

Summary of Discussion:

A committee member asked if there were any specific near misses the MPSC was looking to target with this change in policy. Another committee member asked how the MPSC defines a near miss and thought that it is extremely broad to define. Dr. Turgeon responded that how near misses are defined is up to the MPSC to define and submit to the community for feedback through public comment. Another committee member stated that they thought it was important to limit the scope of near misses.

Vote:

Due to a loss of quorum, the committee did not vote on this project on April 28th. The committee had additional follow up questions about the project which will be addressed during a future meeting. The vote will also take place in a future meeting.

Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates (Histocompatibility Committee)

Dr. Turgeon presented a proposal from the Histocompatibility Committee to Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates to reduce the amount of time it takes for highly sensitized candidates to gain allocation priority, by removing unnecessary documentation requirements for CPRA 99-100% kidney candidates. Currently, programs must sign approval forms and enter data on approving lab directors and surgeons or physicians on the Waiting List before these candidates are eligible for higher sequences on the match run. This policy would allow these candidates to receive allocation

priority according to their CPRA immediately up until continuous distribution is implemented. Current data collection and impact on match run eligibility will need to be addressed for the continuous distribution of kidneys. The project aligns with the strategic plan to increase equity in access to transplants.

The Histocompatibility Committee is currently collaborating on the Continuous Distribution of Kidneys and Pancreata and expects to collaborate with the DAC and Kidney Committee on the project. The committee expects technical implementation hours to be approximately 970 hours. During the POC's review process, they unanimously approved recommending the new project to the Executive Committee. Although the project scored slightly less than the other histocompatibility project, POC members agreed this was also an important efficiency measure to address. The project scored highest in policy priority, vulnerable populations, and the population impacted metrics.

Summary of Discussion:

A committee member voiced their support on the importance of the project and said that the practice was originally used to keep people from gaming the system. They said that it is important to assume the best in situations and then if there is evidence that shows otherwise, then guardrails can be put in place.

Vote:

The Executive Committee approved the initiation of the new project to Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates from the Histocompatibility Committee.

Evaluate Donor and Recipient Histocompatibility Forms (Histocompatibility Committee)

Dr. Turgeon presented the project to Evaluate Donor and Recipient Histocompatibility Forms from the Histocompatibility Committee. The purpose of the project is to add data collection to Recipient Histocompatibility Form (RHF) on virtual crossmatching to increase efficiency of the system through future policy changes and dissemination of best practices. The project will revise Donor Histocompatibility Form (DHF) and RHF to align with current histocompatibility practices. The project aligns with the strategic goal to increase the number of transplants.

The Histocompatibility Committee is currently collaborating on the Continuous Distribution of Kidneys and Pancreata and expects to collaborate with the DAC and Kidney Committee on the project. The committee expects technical implementation hours to be approximately 1,000 hours. The POC unanimously approved recommending the new project to the Executive Committee and said that the project is an important efficiency measure. The proposal scored highest in measurability and policy priority metrics in benefit scoring.

Vote:

The Executive Committee approved the initiation of the new project to Evaluate Donor and Recipient Histocompatibility Forms from the Histocompatibility Committee.

The meeting adjourned.

Attendance

- **Committee Members**
  - Dianne LaPointe Rudow
  - Gail Stendahl
  - Jerry McCauley
  - Jim Sharrock
  - Linda Cendales
  - Lloyd Ratner
  - Matthew Cooper
  - Valinda Jones
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor
  - Christopher McLaughlin
  - Frank Holloman
  - Shannon Taitt
- **UNOS Staff**
  - Anna Messmer
  - Isaac Hager
  - Jacqui O'Keefe
  - Kimberly Uccellini
  - Kristina Hogan
  - Liz Robbins Callahan
  - Matthew Cafarella
  - Meghan McDermott
  - Michael Ferguson
  - Michael Ghaffari
  - Morgan Jupe
  - Roger Brown
  - Ryan Ehrensberger
  - Susan Tlusty
  - Susie Sprinson
  - Tiwan Nicholson
  - Tony Ponsiglione
- **Other Attendees**
  - James Trotter
  - Nicole Turgeon