OPTN Data Advisory Committee
Meeting Summary
March 11, 2024
Teleconference

Sumit Mohan, M.D, M.P.H., Chair
Jesse Schold, PhD., M.Stat., Vice Chair

Introduction

The OPTN Data Advisory Committee met via Webex teleconference on 03/11/2024 to discuss the following agenda items:

1. Public comment proposal: Executive Committee – OPTN Strategic Plan 2024-2027
2. Overview: Deceased Donor Data Collection
3. Data definition revision: "Date Last Seen"
4. Other Committee Business

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

1. Public comment proposal: Executive Committee – OPTN Strategic Plan 2024-2027

The OPTN Vice President presented public comment proposal, the OPTN Strategic Plan 2024-2027.

Summary of discussion:

The OPTN Vice President began the presentation by stating that the OPTN Board of Directors adopts a new strategic plan every three years. The current strategic plan expires in June 2024. The strategic plan is not an exhaustive list of the OPTN's work, but rather serves as a high-level framework to guide the OPTN's strategic focus. For this public comment proposal, the Executive Committee intentionally selected goals with greater specificity to allow for a focusing of resources on key opportunities, driving action to ultimately benefit patients. While building trust through action on opportunities most impactful to the transplant community, the OPTN remains dedicated to our vision. The OPTN promotes long, healthy, and productive lives for persons with organ failure by promoting maximized organ supply, effective and safe care, and equitable organ allocation and access to transplantation; and doing so by balancing competing goals in ways that are transparent, inclusive, and enhance public trust in the national organ donation system. The OPTN Board of Directors commits to achieving the goals outlined in the strategic plan while also staying dedicated to the following points: increasing the number of successful transplants; honoring the selfless gift of life given by organ donors; safeguarding the well-being of patients and living donors, and continuously improving the outcomes of patients on the waitlist, living donors, and transplants recipients.

There are three strategic goals being proposed:

- Improve offer acceptance rates,
- Optimize organ use, and
- Enhance OPTN efficiency.

As it pertains to improving offer acceptance rates the goal is to increase opportunities for transplants by enhancing offer acceptance. There are two objectives for this goal. The first is developing, implementing, and effectively promoting educational programs for patients and transplant programs focused on understanding offer acceptance. The second is to collaborate with stakeholders to improve offer and acceptance processes to increase consistency.

Metrics:

- Increased offer acceptance rates (Overall)
- % of completed learnings (Objective 1)
- % of programs utilizing education offerings (Objective 1)
- Decreased time from first offer to offer acceptance (Objective 2)
- Decreased variation in time from first offer to offer acceptance (Objective 2)
- Decreased number of offer declines (Objective 2)

The Vice President said that improving organ offer acceptance may lead to better transplants and it may lead to less non-utilization, but in and of itself, the goal is intended to help improve the efficiency of the allocation system overall. The Board wants to develop plans that will improve offer acceptance so that organs are accepted by transplant programs at a higher sequence number on the match run, for example. Developing and promoting educational programs for patients is intended to assist patients and their families in understanding what they are saying yes or no to throughout the process, and that they understand the risks and the benefits of various organ offer acceptances.

As it pertains to optimizing organ use the goal is to maximize the use of organs for transplantation for waitlisted patients, while maintaining or improving upon past equity gains. There are three objectives for this goal. The first being to collaborate with stakeholders to identify and reduce key barriers influencing organ non-use. The second is to disseminate and promote best practices and effective strategies for reducing organ non-use across the transplantation community. And the third objective is to explore and evaluate alternative allocation strategies for organs at high risk of non-use.

Metrics:

- Decreased % of organs recovered for transplant and not transplanted (kidney and liver) (Overall)
- Decreased % of organs not recovered for transplant from deceased organ donors (heart and lung) (Overall)
- Maintaining or Improving Equity: Access-to-Transplant Scores (ATS) (Overall)
- Achievement of milestones in identifying and addressing key barriers to organ non-use. (Objective 1)
- Decreased variation of risk adjusted non-use rate by OPOs (Objective 2)
- Decreased High risk organ non-use rate (Objective 3)

As it pertains to enhancing OPTN efficiency the goal is to increase the efficiency of the OPTN through improvement and innovation. There are two objectives for this goal. The first is to refine the policy development and implementation process to be more efficient and strategically aligned. And the second is to enhance OPTN data collection: increasing availability of actionable data while reducing member burden.

Metrics:

- Decreased policy development time (Objective 1)
- Decreased policy implementation time (Objective 1)
- Policy alignment with the strategic plan (Objective 1)

- Stakeholder satisfaction in the policy development process (Objective 1)
- Milestone achievement in data optimization (Objective 2)

The Vice President stated that a goal associated with enhancing efficiency is to right-size the effort and the development process to reflect the size of the changes being implemented.

Some implementation considerations are to recognize the need to prioritize and manage work differently. A Board work group will be launched in early 2024 to refine the project prioritization and approval processes. This plan will be managed by the Board and Executive Committee through regular reviews of strategic plan metric results, review of OPTN resource allocation, and discussion of community needs. This plan is intentionally structured to provide flexibility and latitude to the Board to be responsive to the needs of the community.

The Vice Chair thanks the Vice President for the presentation. The Vice Chair then pointed out that the Data Advisory Committee has spent a great deal of time recently identifying the appropriate pre-waitlist data, specifically referral and evaluation data that should be collected. The Vice Chair went on to say that one challenge with many policies and existing metrics is that they are related to the data that we have historically captured. The OPTN Contractor is trying to maximize outcomes for the waitlist population. This will be more efficient for the waitlist population but the key limitation of that is, we don't know what the denominator is of potential individuals who would benefit from an organ transplant. The OPTN should look to avoid unintended consequence that might shrink who can benefit from transplant opportunities. Or one does not want to limit access to transplant for those who benefit the same parallel on the donor side.

The Vice Chair continued that this point was important to bring attention to and to reflect about the broader population, which in turn will have a better understanding going forward as part of policy development, and whether it be efficiencies or access to transplant equity considerations. The belief is that having this data in place will allow OPTN committees to think more broadly about how these policies will affect a much bigger population. There is hope that there will be discussion with the Board moving forward. The Vice President agreed with The Vice Chair and continued to say that the data directive will help start the development of that denominator. However, there is still work to be done on how we get that data. The advice was taken on at least that portion of it being integrated.

The Vice President continued by saying that each time the OPTN wants to collect new data, it must go through the OMB process. And, it is not clear why the OPTN data collected from members must go through the OMB process. The hope is with the help of this idea we could start to put together rational discussion as to why this data doesn't have to fit into the general larger societal data bucket that has to go through that OMB process. The Vice Chair added to this point that with policy development there should be a hierarchy of changes that would be amenable to a much faster track process. The Vice Chair concluded that he would welcome the opportunity to work with the board regarding this matter. The Vice President ended with the remarks that this feels like it will fit in to the strategic plan of efficiency.

<u>Next steps:</u>

The Committee will submit a formal public comment response concerning the Strategic Plan proposal. It was recommended that the formal response include the Vice Chair's comments regarding how certain policies may affect a larger population and the need for data collection to develop a denominator.

2. Overview: Deceased Donor Data Collection

OPTN Contractor staff presented information about the deceased donor data collection regarding the current state and the proposed path forward for The OPTN Contractor.

Summary of discussion:

The current deceased donor data collection state has three points: cause of death, mechanism of death, and circumstances of death. There are issues with the current state of DDR fields. Specifically cause, mechanism, and circumstance of death in OPTN data is not defined. Although terms are being used, they are not being used correctly. An example is a cause of death is a mechanism of death, but the circumstance of death is unknown. Another issue is that choices offered in lists duplicate across fields. The concepts within the lists are also not mutually exclusive. There is no current guidance that's provided about how to select one stead of the other. Fields are currently mixing concepts from medical pathology unnecessarily.

The proposed path for OPTN Contractor staff is to sponsor a 2024 project to revamp the data collection: cause of death, mechanism of death, and circumstances of death. As well as leverage work already being performed by UNOS Research. And support other committee work dependent upon this data collection.

The OPTN Contractor did not have any formal questions/discussions regarding overview of deceased donor data collection.

Next steps:

The OPTN Contractor will send the Committee members a document outlining the issues and potential path forward within a few days following this meeting. The topic has been added to the agenda of the March 22nd in-person meeting for discussion of the document. The goal is to prepare a project form for submitting to the OPTN Policy Oversight Committee for potential approval to pursue the topic as an OPTN project.

3. Data definition revision "Date Last Seen"

The OPTN Contractor discussed the data definitions/updates regarding date last seen, death, or last seen retransplanted.

Data summary (as applicable):

Date last seen current definitions. Date: Last seen Retransplanted or Death: Enter the date the patient was last seen, the date of retransplant, or the date of death. The date last seen can be obtained from a visit (in-person or virtual), contact with a transplant program representative (e.g., telephone encounter) or an outside healthcare provider. Date Last Seen or Death: Enter the date the living donor was last seen. Date last seen can be obtained from a visit (in-person or virtual), contact with a transplant program representative (e.g., telephone encounter, or an outside healthcare provider. If the living donor died, enter the date of death. Use the standard 8-digit format of MM/DD/YYYY. This field is required. The proposed updates to these definitions are as follows. TRR/TRFs Date: Last Seen, Retransplanted or Death: Enter the date the patient was last seen, the date of retransplant, or the date of death. The date last seen can be obtained from a visit (in-person or virtual), contact with a transplant program representative (e.g. telephone encounter), or an outside healthcare provider related to transplant care. LDR Date Last Seen or Death: Enter the date the living donor was last seen. Date last seen can be obtained from a visit (in-person or virtual), contact with a transplant program representative (e.g. telephone encounter), or an outside healthcare provider related to transplant care. If the living donor died, enter the date of death. Use the standard 8-digit format of MM/DD/YYYY. This field is required.

Summary of discussion:

The OPTN Contractor raised the question of what the concern is as it pertains to data definitions/updates regarding date last seen, death, or last seen retransplanted. The Contractor confirmed that the concern can best be described in an example format. An example is if a transplant patient saw an ophthalmologist or another physician but the visit had nothing to do with the person's transplant, should that date be used as the date last seen? In such cases, the transplant program can be reading back through the notes and then having to determine if that should be related to transplant care. Therefore, the goal is to add a brief phrase to specify that the patient is seeing a nephrologist that is an outside healthcare provider but still related to transplant that then should be considered. The Vice Chair added that there are two different constructs, understanding whether the patient is still alive or if this is a verification that they are still in a healthcare system period versus them receiving transplant specific care. Given the fact that this may or may not correlate well with loss to follow up status, the advantage of the old way is that one knows they are still alive, given imperfect ascertainment of death records. Whereas the second construct is that they are getting some related transplant care. The Vice Chair persisted that both are important. If there was a more robust collection of graph loss and that data, then it could depend on a regular basis, and it would be less than an issue. But the last seen at least will provide some reference if the patient is still alive in that context. The Vice Chair advised there is importance in these factors and that there is not a necessary end point for all patients and being thoughtful about other ways to garden that information is still useful. A member of the OPTN Contractor staff concluded that was a great point and reading through the conversation that occurred in December, it was not decided whether this is just for the patient or is it for the transplant center. That is part of the question and the discussion. The Vice Chair advised that this is on the Transplant Candidate Registration (TCR) form for the sixth month interval and the one-year interval forms. The OPTN Contractor staff member confirmed that it was and, on all organs, as well. The Vice Chair added to this that it's not in real time so to speak it is whether they were seen during that year and for both. A member of OPTN Contractor staff confirmed that was correct.

A member of OPTN Contractor staff had a question if there is any history on why this question is being asked. They continued that they would want to know if the patient has been seen anywhere, because one would know they are still alive. Hence, that's appropriate to change the entire context of how the question is being asked. Therefore, is there any way to go back in time and figure out why that question is being asked at all. Because if we only want to know the patients alive, could one say something along the lines of has there been any contact with a healthcare provider anywhere that would indicate that the patient is alive. A member of OPTN Contractor staff advised that was something they would need to follow up on as well as do research on. However, they did advise that prior to the updates in December 2023 it was also not very clear if the intent was if the patient was alive or is it follow them from a transplant perspective. Another member chimed in and asked if they were to establish this today what would this group suggest. The group would certainly want to know if the patients were still alive. But is it just as important if they are following up for care. The Vice Chair spoke to that and advised it was important given that they have an imperfect system for evaluating whether patients are alive right now. It's another mode of ascertaining that it's important for our endpoints. However, the problem is that they are still receiving care of some sort so its pretty vague. Particularly when it's done in some sort of outpatient facility that is not directly tied to the transplant center. It may be interpreted differently, or there may be variable documentation. Whether it transplant specific care, blood pressure checkups, medications, etc. It's open to interpretation. Just knowing the patient is receiving care, is still living, and is part of the health care system is more objective. A member of OPTN Contractor staff agreed with that perspective and advised that the other item to look for is the long-term outcomes and if that's being measured. The fact that they are still followed within a transplant center, or something related to transplant care versus someone whose outcomes are different because they never saw another person

from the transplant center again. That way if we are using two points to make sure why this question is being asked that would be one way to clarify if the care is somehow related to their transplant management or their visit is related to transplant care.

A member of OPTN Contractor staff advised that another question that has been raised is regarding refill requests and should a transplant center count a refill request from a pharmacy as a date last seen. Another member added onto this that labs would fall into the same area. Which was agreed that transplant centers do consider labs as date last seen. Labs drawn related to the transplant care, not showing up for just a CBC, but they got a CBC and another lab done. Then the data team comps that as a date of classic. A member added to that conversation that it would be difficult to create an A and B option for this question or would that need to go through some sort of approval process to enter the date that the patient was last scene with the caveat of the healthcare provider related to transplant care or date of death. Therefore, those are two separate date points as opposed to one. A member of the OPTN Contractor staff spoke to this that then this would be considered a larger project split. And to split this into two different ones versus just updating the help text. The Vice Chair concluded that based off the conversation it's not worth changing the language. If someone were to get an outside lab and whoever is then entering this form and having to interpret whether that's related to transplant care or not. It will be hard to adjudicate and it's unknown if we're going to learn more from that. And just knowing the patient is still receiving care at some level whether it's specific to transplant or not. It's hard to interpret this particularly as patients go further out.

A member of the OPTN Contractor staff advised that if were collecting this data, in the eyes of transplant outcomes then a patient is last seen because they stuck a pencil in their eye as opposed to, they are following a liver transplant. Those are two very different things, especially if the patient loses their liver transplant the following day. The Vice Chair advised the A&B would be preferred since that having more granular information about what they're being seen for would be important.

The Vice Chair continued that if a patient were to be seen eight years out and they got lab measures done would one feel comfortable that 99% of the time one could say whether it's related to transplant care or not. A member of the OPTN Contractor staff added to this that it's not mandated to complete them indefinitely. Centers are asked to report the data they have but there is a six-month, twelve-month, one-year, and two-year form for living donors. There will be follow up by the OPTN Contractor that the last scene date is being used to calculate post-transplant survival metrics and if someone would substitute last scene, re transplanted, or death as the last known date for survival calculations. The OPTN Contractor will diligently check that this is accurate and is being used in that way. However, that is not to say that this is the only function that this information has in our data, certainly there is a conversation to be had about the best method of collecting this data. Whether does it need to serve a couple of different purposes or one. A member added to this by advising that this would change the data use in time. Such as reporting on these eight-, nine-, or ten-year transplants. Versus more looked upon as last alive, but when one is talking about the one, two, or three years it's more of a useful data point for other data points.

Next steps:

Since multiple members had questions regarding data definitions and help text updates this will need to be discussed further at the in-person March 22,2024 meeting if there is time or discuss this information at the April 8, 2024, meeting.

4. Other Committee Business

Changes to how members access SharePoint occurred on March 11, 2024. Public comment ends March 19, 2024. Special public comment – Executive Committee: Proposal to Address the Relationship of the

OPTN and OPTN Contractor Boards, Open for public comment February 28 – March 13, 2024. March 22, 2024, DAC In-person meeting – Houston Texas.

Upcoming Meeting

- March 22, 2024 (In-person meeting, Houston TX)

Attendance

- **Committee Members**
  - Jesse Schold
  - Jamie Bucio
  - Kate Giles
  - Dustin Goad
  - Michael Ison
  - Paul MacLennan
  - Michael Marvin
  - Christine Maxmeister
  - Meghan Muldoon
  - Hellen Oduor
  - Julie Prigoff
  - Alicia Skeen
  - Allen Wagner
- **HRSA Representatives**
  - Adrianna Alvarez
- **SRTR Staff**
  - Avery Cook
  - Jon Snyder
- **UNOS Staff**
  - Brooke Chenault
  - Marty Crenlon
  - Kevin Daub
  - Viktoria Filatova
  - Cole Fox
  - Nadine Hoffman
  - Sevgin Hunt
  - Sara Langham
  - Krissy Laurie
  - Eric Messick
  - Lauren Mooney
  - Laura Schmitt
  - Holly Sobczak
  - Kim Uccellini
  - Joe Watson
  - Divya Yalgoori
  - Anne Zehner
- **Other Attendees**
  - Rich Formica