OPTN Pancreas Transplantation Committee
Meeting Summary
February 26, 2024
Conference Call

Oyedolamu Olaitan, MD, Chair
Ty Dunn, MD, MS, FACS, Vice Chair

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Cisco WebEx teleconference on 02/26/2024 to discuss the following agenda items:

1. Public Comment Presentation: 2024 – 2027 Strategic Plan
2. Public Comment Presentation: Modify Effect of Acceptance Policy

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

1. Public Comment Presentation: 2024 – 2027 Strategic Plan

The Committee received a presentation on the OPTN Executive Committee's *2024- 2027 Strategic Plan* proposal.

Summary of discussion:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

The Committee Chair commented that upon review of the proposal, the first and second goal of the proposed strategic plan seemed to be similar, however, after the presentation, there was an understanding of the two goals being separate, but the end goal being the same in increasing the number of transplants and optimizing utilization. Additionally, the use of artificial intelligence (AI) should be considered since this proposal is very information technology (IT) heavy and process related. With the current climate, there is an increased burden on the human component of organ offers. The use of AI could potentially help with increasing efficiency and decreasing the work on the individual organ procurement organization (OPO) and transplant hospital staff.

The presenter agreed with this and commented that the better use of improved technology and innovation is integral to the success of all the goals outlined in the strategic plan. As the OPTN Expeditious Task Force (Task Force) moves forward and identifying some of those opportunities, they will facilitate some of these broader goals that are anticipated to be focused on in the future.

A member summarized their understanding of the first two goals to being a) offer acceptance is when a transplant program has criteria set for a particular organ being accepted or not and b) optimization is more related to non-use of an organ.

The presenter agreed with this summary and stated that there were nuances that would be reflected in both goals. There should be a focus on organ acceptance and when looking at what those initiatives are, it would be in providing education to transplant programs, so they have the information they need to make the decisions they need to. With the changes in allocation seen and data that has been monitored, there has been an increase in organ non-use observed. This relates to logistical and operational issues

(i.e. transportation, cold time, etc.) that the second goal of the Strategic Goal anticipates addressing. The presenter added that there is a strive for perfection, but progress is needed; even with the changes with allocation, there have been unintended consequences. The proposed goals are to improve the existing system to increase overall the opportunities for transplants for patients.

The member continued by asking if the Executive Committee expected the OPTN Committees to develop a strategic plan on projects to be in alignment with the goals outlined. The presenter confirmed that the future vision is that with the development of the strategic plan, the OPTN Committees would review and identify, based on their expertise and knowledge collectively, opportunities and/or initiatives in which change could be affected in those areas. Staff added that the Committee will come back to this point during the in-person meeting to discuss potential projects that could be pursued.

A member asked how the achievement of these goals would be precisely measured. The member noted that currently, OPOs have become increasingly aggressive in the offers they pursue. The presenter stated that when talking about organ use, having definitions to help in standardization is important. The Task Force are looking at various methods (i.e. plan-do-act studies (PDSA's)) to gain insight on processes being done across programs. These goals are looking to identify best practices, what is safe, appropriate and the right way to increase these opportunities of transplants. Unrealistically, the goal would not be 100% globally, and it would be helpful to hear from the Committee on providing education and data that would help share what types of organs should be offered/accepted.

A member commented that as deceased donors have increased over the years, there are opportunities lost to living donation, which is the best option for long term outcomes. There are some concerns with the use of these organs, that are sometimes marginal, in the long-term outcomes. Additionally, risk adjustment metrics (i.e. KDPI), don't necessarily reflect the organs that are being accepted currently, especially in long-term outcomes; there would need to be some change in this outlook moving forward. The member also suggested some adjustments made to the recipients who may have an inferior outcome due to the quality of the organ transplanted.

The presenter replied that these goals are broad based, and it is important to identify specific projects such as looking at risk adjustment. Additionally, there should be work done with commercial payers. Similarly, there is discussion on novel technology – if high technology enhancements are being used, it poses the question of where these costs lie. The member agreed with these additional focus points as these could have negative impacts if not monitored.

The presenter continued by adding that what has not been mentioned in the presentation, but is evident, is that everyone has a finite budget (i.e. OPTN, OPOs, transplant hospitals, etc.) and working with limited resources. The goal is to determine how to work collaboratively to overcome some of the challenges to streamline care and affect changes. A member commented that reaching out to the C-suite of every institution would be important. The presenter stated that one of the goals of the payer group is to try to get a playbook for programs (OPO and transplant hospital versions) that would share some of this high-level information with C-suite teams.

Another member asked if there were more numerical metrics that would be evaluated and what that looks like for the goals outlined. The presenter confirmed that this would be done and stated that currently there is a prolonged process for policy development that is written into the regulations for the OPTN and HRSA. The proposal will be to quantify this and have some reduction of this. There has been criticism over the years (anecdotally), that it takes too long to make changes. There will be a baseline measurement and the proposed goals will be used to quantify what that numerical rate would be in terms of reduction/improvement.

<u>Next steps:</u>

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

2. Public Comment Presentation: Modify Effect of Acceptance Policy

The Committee received a presentation on the OPTN Ad hoc Multi-Organ Transplantation Committee's *Modify Effect of Acceptance Policy* proposal.

Summary of discussion:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

A member asked what would happen to a transplant hospital's acceptance rate if the transplant hospital had to reallocate an organ. The presenter clarified that this is the point of the proposal – the organ would not be taken back from the primary kidney that was accepted. The Committee Vice Chair clarified further that to the actual question posed, the heart-kidney patient that would be next on the waiting list that would not be offered the heart-kidney (because the kidney would not be available to them), would be bypassed coded and would not be counted against the program's acceptance rate. The presenter added that the organ would still be offered, but if the program declined the offer, it could be declined because multiple organs were not available. Sometimes, the patient could have the heart or liver transplant without a kidney and would not want to bypass those patients. The presenter added that there will need to be education that would be included in the implementation plan.

Another member asked that if this scenario should happen as described, the program should not be penalized in their acceptance rate because there would be a reasoning why the organ was not accepted. The presenter replied that the decline code should exclude a program from having an acceptance rate penalized.

A member agreed with the other comments in this proposal being a good move forward to address efficiency issues. The member commented that on occasion, this can also be an issue for pancreas. There is some idea in thinking about what an acceptable pancreas cold ischemic time (CIT) is; if there is a liver-kidney and some thoracic-kidney offer, the pancreas-kidney list can be tied up as well. The presenter agreed with this and stated that this would also be a good example to share. If there is a liver-kidney and a heart-kidney and the next patient on each list needs a kidney, OPOs tend to hold those kidneys, which disadvantages the pancreas at that point as are those top single kidney patients on the list.

Staff clarified that offers to multi-organ candidates are excluded from the offer acceptance metrics except for the kidney-pancreas (KP) candidates who are also listed for kidney alone.

A member asked if a KP patient was also listed for kidney only, does this mean that the acceptance rate would be impacted by turning down the kidney for KP? The member continued by stating that the waiting time for a pancreas alone has increased, so if a KP patient passes on kidney alone to wait on the next KP, would the program be impacted by this? Staff stated that all multi-organ combinations are excluded from acceptance rate performance metrics except for KP. For example, if a heart is declined and the next offer is a heart-kidney and it was declined, it would not be reflected in a program's acceptance rate. The member followed up by stating that it may be the way that programs are listing patients and asked that if programs only wanted KP patients rather than kidney alone, would the

program need to remove the kidney portion when listing patients? Staff confirmed that this would be correct and stated that it was believed this was standard practice across programs. Staff summarized for clarification of the question that the example entailed a kidney alone on a kidney match would decline no matter what because the program is looking for a KP offer. The member confirmed this was the scenario they were referring to. Staff commented that this could potentially impact program practices but could not speak to program practices holistically to this extent. It was noted that the acceptance rate is risk adjusted which may have a benefit here, but this would need to be looked into further to confirm if KP candidates on a kidney match are excluded as well.

The Committee Vice Chair stated that in thinking about this, there is some bidirectionality when it pertains to KP, the pancreas is not the lifesaving organ. In contrast to the other examples provided, the program would not move forward with the pancreas alone. The offer may move forward with a kidney alone; however, it may not be the best thing for the patient based on what is already known about outcomes for deceased donor kidneys and pancreas after kidney. The Committee Vice Chair continued that this should be looked at as something that is unique to KP and considering what would be an exclusion for this. Staff will look into this further to provide the Committee with more information on this.

A member asked that for the acceptance that is being referred, does this include a definite acceptance or provisional yes. The presenter confirmed that this is in reference to a definite acceptance. The member continued by stating that in clarifying the criteria where a single organ candidate will take precedence over a multi-organ candidate and voiced agreement that for KP candidates, there could be criteria related to living donor or a high CPRA, etc. A best practice still could be where the OPO discusses the scenario where there is a heart-kidney waiting for an offer and coming to an agreement with the transplant program to send that kidney to the multi-organ candidate. Otherwise, this could cause conflict.

The presenter stated that in response to the feedback on the pancreas vs. KP being included in multi-organ combinations, it would be helpful to include in the other OPTN Ad hoc Multi-Organ Transplantation Committee's concept paper, *Concepts for Modifying Multi-Organ Policies* that is also out for public comment.

Next steps:

The Committee's feedback will be synthesized into a formal statement that will be submitted for public comment.

Upcoming Meetings

- March 8, 2024 (in-person (Houston, Texas))

Attendance

- **Committee Members**
  - Oyedolamu Olaitan
  - Ty Dunn
  - Asif Sharfuddin
  - Colleen Jay
  - Neeraj Singh
  - Girish Mour
  - Jason Morton
  - Dean Kim
  - Diane Cibrik
  - Jessica Yokubeak
  - Nikole Neidlinger
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jon Miller
  - Bryn Thompson
- **UNOS Staff**
  - Joann White
  - James Alcorn
  - Cole Fox
  - Houlder Hudgins
  - Kaitlin Swanner
  - Lauren Motley
  - Linsday Larkin
  - Sarah Booker
  - Sarah Roache
- **Other Attendees**
  - Andrea Tietjen
  - Lisa Stocks