OPTN Organ Procurement Organization Committee
Meeting Summary
September 21, 2022
Conference Call

Kurt Shutterly, RN, CPTC, Committee Chair
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Introduction

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 09/21/2022 to discuss the following agenda items:

1. Welcome
2. Public Comment Presentation: *Update on the Continuous Distribution of Kidneys and Pancreata*
3. Public Comment Update: *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection*
4. New Project: Limit Organ Offer Acceptances
5. Organ Tracking Project Idea

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

1. Welcome

Committee leadership welcomed the Committee members.

Summary of discussion:

The Committee had no questions or comments.

2. Public Comment Presentation: *Update on the Continuous Distribution of Kidneys and Pancreata*

The Chair of the OPTN Kidney Transplantation Committee presented the *Update on the Continuous Distribution of Kidneys and Pancreata* currently out for public comment.

Presentation summary:

The *Update on the Continuous Distribution of Kidneys and Pancreata* will inform the community on the progress of the continuous distribution project. The paper highlights further detail on proposed attributes and rating scales, an overview of the analytic hierarchy process (AHP) results, considerations for allocation components outside of the composite allocation score, and the Committee's first modeling request.

Continuous distribution will:

- Provide a more equitable approach to matching kidney and pancreas candidates and donors
- Remove hard boundaries between classifications that prevent kidney and pancreas candidates from being prioritized further on the match run
- Consider multiple patient attributes all at once though a composite allocation score instead of within categories by sequence
- Establish a system that is flexible enough to work for each organ type

The previous request for feedback was accompanied by a call to action in participation of two AHP exercises. The AHP is a values prioritization exercise that asked participants to weight attributes against each other. There were two exercises available during public comment – one specific to kidney and one specific to pancreas and kidney-pancreas (KP).

The AHP results for the Kidney exercise showed that medically urgent candidates received the highest rating, with placement efficiency receiving the lowest rating. The AHP results for the Pancreas and KP exercise showed the most weight going to candidate biology and difficult to match candidates, with the least weight going to proximity efficiency.

Data, public comment, and AHP results were considered in order to finalize rating scale recommendations (see **Tables 1 and 2)** for outstanding attributes and develop draft frameworks for modeling. The first round of modeling was submitted in April, and will test the effects of what would happen in extreme cases. The next round of modeling will be more detailed and granular.

Table 1: Kidney Rating Scales

Attribute	Rating Scale
Medical Urgency	Binary
HLA Matching	0, 1, or 2 DR mismatch
Longevity Matching	Continuous longevity matching
Blood Type	Current screening and blood type points
Calculated Panel Reactive Antibody (CPRA)	Steep non-linear curve
Prior Living Donor	Binary
Pediatrics	Binary
Kidney after Liver Safety Net	Binary
Qualifying Time	Linear, exceeds 100 percent beyond 10 years, no cap
Proximity Efficiency	Piecewise linear, 50 nautical mile (NM) inner plateau, 85 percent at 250 BM, 25 percent at 500 NM, and 0 percent at 5181 NM

Table 2: Pancreas and KP Rating Scales

Attribute	Rating Scale
Blood Type Identical	Relax KP screening and identical before compatible
CPRA	Steep non-linear curve

Prior Living Donor	Binary
Pediatrics	Binary
Qualifying Time	Linear to curve. Inflection point: 90 percent at 5 years, with a the shallower line beyond 5 years to max
Proximity Efficiency	Piecewise linear, 50 NM inner plateau, 25 percent at 250 NM, 0 percent at 5181 NM
Whole Pancreas (KP/PA), not Pancreas Islets	Binary

Current kidney allocation and prioritization differs depending on the donor kidney's kidney donor profile index (KDPI). To replicate this, the Kidney Committee is incorporating weight modifiers depending on donor factors. These weight modifiers are included in the Kidney Pancreas Simulated Allocation Modeling (KPSAM) and serve to replicate priority in existing KDPI sequences for kidney. Similarly, the Pancreas Committee will also be incorporating weight modifiers for donor factors specific to pancreas, namely donor age and body mass index (BMI).

For the first round of modeling, the Kidney and Pancreas Committees were limited to five scenarios or runs. The following runs were requested:

- Run #1 – model of current classifications-based policy to use as a baseline
- Run #2 – combined community feedback results. The community's AHP results are combined with Kidney and Pancreas Committee-specific results to model draft weights for each attribute.
    - Also incorporates expanded longevity matching, pediatric priority for KDPI 35 to 85 percent pediatric kidneys, and a steeper CPRA curve
- Run #3 – increased weights for longevity matching and post-transplant survival in Kidney allocation
- Run #4 – increased weight for placement efficiency
- Run #5 – increasing weight modifiers for high KDPI kidneys, to focus on increased proximity efficiency for hard to place kidneys

The paper also includes an overview of allocation components that fall outside of the composite allocation score, to include dual kidney, en bloc kidneys, facilitated pancreas, mandatory KP offers, national offers, screening and filters, released organs, and review boards.

The Kidney and Pancreas Committees will review the KPSAM results and make adjustments as needed and re-submit for additional modeling. The Kidney and Pancreas Committees will continue to update the community on the progress of the project. Public comment received will be reviewed and considered in development of a framework and eventual proposal.

Summary of discussion:

One member expressed support for improved and more efficient pancreas allocation. Several members emphasized the importance of placement efficiency, particularly in light of impacts to efficiency in the circles-based distribution. The member recommended the Kidney and Pancreas Committees consider transplant center density as an attribute, which could improve allocation efficiency. The member noted that continuous distribution will need to emphasize placement, transportation, and allocation efficiency

in order to make broader sharing possible and practical. The member commented that high KDPI kidneys and low KDPI kidneys should not be allocated in the same way, and that allocation for high KDPI kidneys should place more emphasis on those centers who will accept those kidneys. The member recommended the Kidney and Pancreas Committees consider how to establish ground rules of engagement between OPOs and transplant programs to highlight transplant programs' role in getting a kidney utilized, even if the organ is not transplanted at their program. The member also recommended the Kidney and Pancreas Committees consider how to encourage increased cooperation between both transplant programs and OPOs.

The Chair of the Kidney Committee shared that the kidney donor profile index (KDPI) calculation will be under scrutiny for the inclusion of certain variables, and that the KDPI calculation is a "zero sum" calculation. If one variable is removed, the other variables will become more important, and some donors with a KDPI higher than 85 percent would then fall below KDPI 85 percent, and vice versa. The Kidney Committee Chair also noted that one aspect of placement efficiency to consider is whether or not the local airport is a hub with multiple flights, or whether connecting flights are required to and from the airport. The Kidney Committee Chair agreed that distance is not precise as a measure of efficiency. The Kidney Committee Chair explained that donor modifiers can be used to improve efficiency in allocation as well.

The Chair thanked the Kidney Committee Chair for their presentation.

3. Public comment Update: *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection*

The Committee received an update on the public comment feedback gathered thus far on the *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection* proposal.

Presentation summary:

Thus far, 10 of 11 regions have received a presentation on the *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection* proposal, and several presentations have been given to other OPTN Committees. Public comment ends on September 28, 2022.

The main themes in public comments submitted thus far include general support, collection of normothermic regional perfusion (NRP) data, recognition that data burden will not be high, and agreement that this information will be useful.

Next steps include continued monitoring of the comments, evaluation of post-public comment changes, Committee vote in October, and then review and vote by the Board of Directors in December.

Potential post-public comment changes to consider include:

- Adding a validator question – such that the donor is only collected for controlled DCD
- Add NRP information (NRP recovery – yes/no; initiation of reperfusion – date/time)

Summary of discussion:

The Chair shared that, during the presentations Committee leadership has given, most of the feedback was about collecting additional data for NRP. The Chair expressed that the Committee should probably seriously consider some kind of related NRP data collection. The Vice Chair added that there were also suggestions to include not just a controlled DCD question, but also a question to capture additional DCD categories.

4. New Project: Limit Organ Offer Acceptances

The Committee discussed a new project to limit organ offer acceptances.

Presentation summary:

The Policy Oversight Committee approved this project on September 12, 2022. A Workgroup is being formed with collaboration between the OPO Committee, the Transplant Coordinators Committee, the Operations and Safety Committee, and the Organ-specific Committees.

Summary of discussion:

Several committee members expressed support for this project, including a few members who volunteered to join a Workgroup for this project.

There were no additional questions or comments.

5. Organ Tracking Project Idea

The Committee discussed potentially working on a new project regarding global positioning system (GPS) tracking in organ transportation.

Discussion questions:

- Should GPS organ tracking be addressed by the OPTN?
- If so, how should this be addressed/potential project ideas that should be considered?
    - OPTN policy, guidance, or other considerations?
- If not, what concerns are there that should be considered?

Summary of discussion:

The Vice Chair noted that it would be difficult to monitor compliance for OPOs that choose not to use the tracking tool offered by the United Network for Organ Sharing (UNOS).

The Chair pointed out that most OPOs are using GPS organ tracking to a certain point, but that the cost of the tracking must be considered. The Chair noted that it would need to be brought to a level where it was feasible for all OPOs to use when shipping kidneys.

One member remarked that it is likely too early for a policy change, noting that many organs are not lost in transport, but instead are delayed. The member recommended that instead a white paper or guidance would be more appropriate, to share best practices. The member noted that most trackers are great, but not where they could be, and so a policy change may be premature. The member commented that OPOs should be encouraged to head in that direction as much as possible.

The Vice Chair explained that the UNOS tracking team is getting close to having useable quantities of data from tracking organ travel. The Vice Chair pointed out that previously, cross clamp time and anastomosis time are known, but that the time in the middle is largely untracked and unexplained and the tracker can provide some insight. The Vice Chair continued that the Committee should consider that organ tracking doesn't just help find the organ in the moment, but also helps establish how organs move, where they move, and what happens to them. The Chair agreed. Other members agreed that the data gathered via organ tracking would be important and helpful.

A member commented that there is a need to foster formal communication with major airlines and other carriers about the urgency and importance of safe and timely transportation of organs as a priority in transplantation. Other members agreed.

One member shared that they had experience initiating the use of GPS trackers with the National Kidney Registry (NKR), and that it was difficult even in that small group. The member continued that doing it on a nationwide scale would be difficult and costly, with many trackers lost. The member explained that a lot of these issues have to do with logistics, and that more support is needed from CMS at a national level, particularly when it comes to airlines. The member expressed that the passion for trackers needs to be redirected to solving some of these other issues. The member shared a recent experience, where a kidney being shipped to a 100 percent CPRA candidate who hadn't received another offer was locked out of the airline by four minutes, due to paper work issues. The member explained that addressing this kind of issue would be significantly more impactful than the trackers. The member added that education would be important as well.

One member noted that it's important for OPOs to be proactive to address this issue before it becomes a requirement for OPOs. The member pointed out that the tracker can indicate that the organ is sitting on the airport tarmac, but not actually address how to get the organ transported. The member noted that trackers were a topic of conversation at the site surveys done by the Centers for Medicare and Medicaid Services (CMS). Another member agreed, noting that there may be a way to address this on multiple levels. The member agreed that it wasn't wise to mandate the use of trackers and that more conversations with the airline industry are necessary to figure out how airlines may be able to help address the problem. The member agreed that the OPO Committee needs to take on some kind of discussion about this.

Staff clarified that this is an initial discussion and request for feedback phase, and noted that it seems the Committee is in support for continuing discussions and potentially a project. Staff shared that all of these ideas are on the table for the Committee to determine the best approach.

One member asked if the Committee could make a referral or recommendation for parties that are not members of the OPTN. Staff confirmed that the Committee could do so. Another member commented that a guidance document is a good way to go, and that if a policy change was needed, it would be easy for the Committee to adjust the project solution.

The Chair expressed support for the direction the Committee is headed with this concept. The Chair noted that it would be important for such a project to consider ensuring that trackers are returned to OPOs. The Chair shared that their OPO always has issues getting them back, even when providing the transplant programs with envelopes. Other members agreed, noting that it is difficult to ensure trackers are returned.

One member noted that their OPO asks the courier to remove the tracker from the box when the organ is delivered and drop it in a mail box to be shipped back to the OPO.

Another member recommended charging transplant programs for failing to return the trackers, such that programs who don't return or lose the trackers have to buy a new one for the OPO. The Vice Chair shared that their OPO does this, and it's a little contentious. The member responded that a potential policy could be that the transplant program would be responsible for the cost of the tracker if not returned.

One member noted that these conversations are being held in the public perception, and that some of this is coming from the transplant program side. The member explained that it is also important to educate the airlines and the transplant programs that OPOs can only rely on the systems that exist. The member expressed support for creating a policy that would require transplant programs to return trackers, noting that there needs to be some kind of accountability on the transplant program side.

Another member supported accountability for both transplant centers and OPOs, as one can't work without the other. The member agreed with earlier comments noting that trackers won't solve issues where the organ is delayed, but that it may help to understand how the organs are traveling. The member pointed out that the NKR puts a cell phone in the box with living donor kidneys – the connection cuts out while on the plane, but it picks back up as soon as the place lands and can help solve the problem once the organ is off the plane. The member shared that their program has had to intercept kidneys from couriers who were lost or confused on where to go.

The Vice Chair recommended forming a subgroup to discuss working directly with airlines. The Vice Chair asked if the OPTN is already having ongoing discussions with airlines. Staff shared that the OPTN Organ Center has had some specific conversations with specific airlines directly, but there hasn't been much response from the airline. Staff noted that there may be more momentum with the backing of the full Committee or a request to move in that direction. One member asked, since this conversation has occurred at higher levels of government, if there was any role for those in congressional committees to work with the Federal Aviation Administration (FAA) and other responsible agencies about these issues. The member noted that a government mandate may carry more weight. Another member remarked that it might be necessary to engage the Department of Homeland Security.

A representative of the Health Resources and Services Administration (HRSA) noted that before September 11, 2001, the organs were placed in the cock pit of the plane. Subsequently, organs shipped via commercial airline were put in the cargo shipping area. The HRSA representative suggested that potentially where the organ is on the plane could be addressed with the airlines.

One member noted that the tracking of organs was of interest to the Senate Finance Committee because of the rules Homeland Security put into place. The member pointed out that the most up to date devices are not allowed on planes due to Homeland Security measures. The member agreed that other discussions are necessary with other federal agencies and major stakeholders in the transplant process. Another member noted that the number of kidneys flown now must be significantly higher than the number flown before September 11, 2001. The member pointed out that it also unreasonble to expect a pilot to have three kidney boxes in the cockpit, particularly when they have limited room there already.

A member asked where on-board couriers on a connecting flight store the kidney box, noting that the box would be too large to fit in the overhead. The Vice Chair shared that, when using an on board courier, they buy a separate seat for the kidney. The Vice Chair noted that the kidney may also be stored in the coat closet up front. The member responded that potentially it could get into the cabin without the courier. The Vice Chair agreed this would be nice, adding that the cost of an onboard courier is very high. Another member agreed.

Upcoming Meeting

- October 6, 2022 – Richmond, VA

Attendance

- **Committee Members**
  - Kurt Shutterly
  - PJ Geraghty
  - Bruce Nicely
  - Chad Ezzell
  - Clint Hostetler
  - David Marshman
  - Debra Cooper
  - Donna Smith
  - Doug Butler
  - Erin Halpin
  - Judy Storfjell
  - Larry Suplee
  - Malay Shah
  - Leslie McCloy
  - Meg Rogers
  - Sam Endicott
  - Sharyn Sawczak
  - Sue McClung
  - Valerie Chipman
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Adriana Martinez
  - Vanessa Arriola
- **SRTR Staff**
  - Ajay Israni
  - Katie Audette
- **UNOS Staff**
  - Robert Hunter
  - Kayla Temple
  - Isaac Hager
  - Joann White
  - Katrina Gauntt
  - Kevin Daub
  - Krissy Laurie
  - Lauren Mauk
  - Lindsay Larkin
- **Other Attendees**
  - Martha Pavlakis