

OPTN Organ Procurement Organization (OPO) Committee

Meeting Summary

March 15, 2022

Chicago, IL

Kurt Shutterly, RN, CPTC, Chair

PJ Geraghty, MBA, CPTC, Vice Chair

Introduction

The OPTN Organ Procurement Organization (OPO) Committee met in Chicago, IL on 03/15/2022 to discuss the following agenda items:

1. Imminent and Eligible Death Data Definitions
2. Technology Tools Project Update
3. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation
4. Provisional Yes Project Update
5. Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B
6. Redesign Map of OPTN Regions
7. Policy Oversight Committee Update
8. Kidney-Pancreas Allocation Question
9. Continuous Distribution of Kidneys & Pancreata Request for Feedback
10. Overview of Analytical Hierarchy Process (AHP) for Kidney/Pancreas Continuous Distribution
11. Offer Filters Project

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

1. Imminent and Eligible Death Data Definitions

The Committee discussed the collection of imminent and eligible death definitions and how the new Centers for Medicare and Medicaid Services (CMS) regulations affect this reporting requirement.

Summary of discussion:

Staff provided background information about how the current imminent and eligible death data definitions were developed. This included:

- Collection of patient-level data for all imminent and eligible deaths – January 2008
- Periodic review of data demonstrated inconsistencies
- Revisions to the definitions developed over several years
- Distributed for public comment in September 2011 and September 2012
- Approved by the Board of Directors in June 2013
- Implemented on January 1, 2017 following CMS regulatory changes

Scientific Registry of Transplant Recipients (SRTR) staff provided an overview of the regulatory requirements for data collection by transplant hospitals and OPOs. SRTR staff noted the upcoming changes by CMS to move to a cause, age, and location (CALC) method based metric. They also noted

that the SRTR website¹ currently publishes eligible and imminent death metrics. Finally, SRTR staff noted that they are willing to work with the Committee to develop better metrics.

A member commented that if CMS no longer recognizes eligible deaths, then there is little reason for the OPTN continue to collect the data. Another member agreed and commented that OPOs have been criticized for “self-reported” data, which includes imminent and eligible data reporting.

A member commented that OPOs only use it for required reporting, while there are plenty of additional data sources for donor potential. Another member added that imminent and eligible death data is not as valuable as true donor potential and will not have much value moving forward when OPOs are evaluated by the new metrics.

A member expressed support for working with the SRTR to identify new metrics. He added that the current eligible definitions only apply to donation after brain death (DBD) donors, and does not include DCD donors. Additionally, the member provided an example of COVID positive donors that do not meet the eligible definition that could now successfully donate organs.

A member suggested that one reason to keep collecting imminent and eligible death data is the concern about death certificate data and its ability to identify potential donors. She noted that it would allow OPOs to have data to identify patients that were not truly eligible donors.

The Committee discussed the best approach to replacing imminent and eligible death data collection with some other form of metrics. There was general support for forming a workgroup to discuss the issue and identify a path forward. This includes developing a project plan that would need to go through the standard policy development process. This includes submission of a project form to the Policy Oversight Committee and working with the Data Advisory Committee and SRTR. SRTR staff noted that while there is value in having replacement metrics, they want to make sure it makes sense to collect it and that it adds value to the community.

The Vice Chair suggested that addressing imminent and eligible death data and new metrics be done as separate efforts. The Committee supported this approach.

The Chair asked how the observed to expected calculator might be impacted by future changes. He noted that it prevents challenges because his OPO still pursues “one organ” donors. A member noted that his OPO uses it because the SRTR publishes it and it is part of their strategic goals. Another member agreed and noted if it was not available, there are other sources of data. Members agreed that this could be part of the larger discussion about new metrics.

Next Steps:

- Internal discussions about impact of eliminating imminent and eligible data reporting
- Begin development of a project form to future project approval consideration by the Policy Oversight Committee

2. Technology Tools Project Update

The Committee received an update on the Technology Tools Project that was recently approved by the Policy Oversight Committee.

Summary of discussion:

Staff provided an overview of the recent discussions by the workgroup.

¹ <https://www.srtr.org/>

- *January 24, 2022* – Workgroup discussed prioritization of the data elements to address resource constraints for this project
- *February 16, 2022* – OPO Committee agreed to remove changes to infectious disease testing in order to adjust the resource estimates to meet available resources. The Committee agreed to move forward with changes and additions to the following items in DonorNet®:
 - DCD information
 - Medications and fluids
 - Echocardiogram and hemodynamics
- *March 3, 2022* – Workgroup discussed the DCD information and provided recommendations on the following data elements:
 - Withdrawal of life sustaining medical support – add date/time
 - Cessation of circulation – add date/time
 - Pronouncement of death – add date/time
 - Aortic flush time (in situ) – collect data similar to deceased donor registration
 - DCD Hemodynamic information – focus of blood pressure and heart rate
 - Hemodynamic information – reorganize transplant center view

A member asked if there would be a new section within DonorNet for the DCD information. Staff noted that part of the workgroup discussions was to identify the best location for both data entry by OPO staff and review by transplant hospital staff. A member suggested that the workgroup also consider how the data can be uploaded directly from the OPO's electronic data records.

Next Steps:

The Workgroup will continue to discuss this data collection project with the goal of submitting a proposal for public comment in August 2022.

3. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation

The Committee was provided with an overview of the *Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation* public comment proposal sponsored by the Ad Hoc Multi-Organ Transplantation Committee.

Summary of discussion:

The Committee supports this proposal and improved clarity and consistency in multi-organ allocation across organ combinations. The Committee agrees that these criteria are reasonable, and important to appropriate allocation of abdominal organs in multi-organ combinations. Some members recommended re-evaluating the SLK required-share circle size, to align with the proposed circle size for heart-kidney and lung-kidney. Staff noted that this would not be in the scope of this proposal, and would require a re-evaluation of the SLK policy, which addresses a much larger volume of patients. Several members noted that efficiency and clarity in multi-organ allocation is critical to improving utilization of high KDPI kidneys.

4. Provisional Yes Project Update

Committee members serving as representatives on this workgroup provided an update on the Operations and Safety Committee's provisional yes project.

Summary of discussion:

Workgroup discussions have included the following:

- Identifying challenges related to provisional yes

- Developing a tiered framework and outline of associated responsibilities of transplant programs
- Identifying potential policy modifications focused on:
 - Defining/outlining specific expectations of members (transplant and OPO)
 - Defining/outlining expectations pre- and post-recovery
 - Ensure terms are clearly defined (ex. provisional yes, backup offers, primary offers)
- Tiered approach within provisional yes
 - Tier I (primary offer)
 - Tier II (back up offer)
 - Tier III
- Policy would include:
 - Defining and outlining requirements of each tier of provisional yes
 - Clarifying and outlining requirements of primary and backup offers
- Potential system changes discussed:
 - Push notifications/alerts
 - Indicating transplant program has reviewed offer and what (if any) additional information may be needed to make final decision
 - Transplant programs being able to see where they fall on match run (expanding current DonorNet mobile functionality)
 - Offers that are a part of multi-organ transplantations (MOT)
- Workgroup will continue reviewing current OPTN policy and discuss potential modifications

A member commented that this work is a great way to address the challenges facing OPOs when placing organs. Another member responded that the workgroup is evaluating ways to show the transplant centers where they are on the match run so they can evaluate offers more realistically. For example, the surgeon might not be contacted after the initial notification, but will be contacted once they get to a Tier 2 offer.

A member noted that from a transplant center perspective, they are evaluating offers with insufficient information. The OPO will send the offer with the information available, but then the surgeon decision changes once they evaluate the anatomy and biopsy. The kidney might look good on paper but the biopsy results indicates we need to go to a different candidate.

A member noted that kidneys are the exception with that new information and the bigger frustration is trying to figure out who is going to accept and recover the heart and lungs. They added that there is more concern with the extra-renal organs when there is new information in the operating room (OR). A member responded that liver size and biopsy results are typically not known prior to the OR.

A member commented that many centers want to know how many centers are between their candidate and the primary offer, as this is a better indicator of priority. Another member agreed, as kidney allocation can involve allocation through as many as 70 kidney programs within the 250 nautical mile (NM) circle. He further added that not all provisional yes responses are equal – some centers might look at every candidate while others use third-party vendors to screen offers.

A member suggested there be more than just a provisional yes response. For example, some response where the OPO knows the offer has been evaluated as outlined in the proposed Tier 2 responsibilities.

The Committee discussed how many potential transplant recipients (PTRs) should be within each tier. One member suggested that Tier 1 include PTRs ranked 1-5, Tier 2 include PTRs 6-10, and Tier 3 is all PTRs starting at 11. Another member suggested the numbers be based on organ type. For example,

heart offers might have 2-3 backups while kidney offers might have 10-20 backups. Several members agreed with that suggestion.

The Chair asked if the issue of multiple offers is being considered by the workgroup. A member responded that system changes are being considered with responsibilities identified for transplant centers.

A transplant center member expressed frustration with other transplant centers that do not review offers until their candidate becomes primary. He expressed support for requiring transplant centers receiving Tier 2 offers to review the offers. Another member noted that some third-party organizations have different processes for when to contact the decision-makers at the transplant centers.

A member commented that his OPO has started tracking their primary offers and found that 50% of the time they are declined and 50% of the time they are transplanted. Another member added that it is helpful to allow transplant centers a chance to request what they need because OPOs want to get organs transplanted. However, marginal organs are sometimes put at risk in favor of perfect organs.

5. Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B

The Liver Committee Vice Chair provided an overview of the *Improving Live Allocation: MELD, PELD, Status 1A and Status 1B* public comment proposal from the Liver and Intestinal Organ Transplantation Committee.

Summary of discussion:

The goal of this proposal is to create a more equitable and efficient liver allocation system by updating the following:

- Model for end-stage liver disease (MELD) score
- Pediatric end-stage liver disease (PELD) score
- Status 1A and 1B requirements

The Committee did not have any comments or questions.

6. Redesign Map of OPTN Regions

The Committee was provided with an overview of this public comment proposal from the OPTN Executive Committee.

Summary of discussion:

Several members expressed support for establishing continuity between donor service areas and OPTN regions. A member agreed, recommending that the regions consolidate OPO DSAs, such that no DSA is split between two regions.

One member noted that fewer regions could be more cost effective to administer. A member recommended the Executive Committee consider which centers and OPO work with each other most often, to encourage effective relationship building. Another member similarly noted that isolating certain states, such as Texas or California, could be detrimental to transplant center and OPO relationship building, and reduce learning opportunities between OPTN members. Several members agreed that fewer regions could challenge productivity of OPTN regional meetings, particularly if regional meeting sizes reach more than 500 members.

Members expressed support for increased consideration of access and equity in the regional redesign project, particularly among disadvantaged patient populations. Members noted that this project will affect patient representation in OPTN Committees and Board of Directors. A member remarked that the

regions should be representative of the demographics and interests of the patients within the regions; Kentucky, for example, is more aligned with the South or Southeast as far as patient and donor demographics than with Texas or Pennsylvania. A member noted that the proposed maps place too much emphasis on relationships between OPOs and transplant programs over the interests and demographics of the patient populations.

Several members expressed concern that fewer regions could dilute the representation that each organization has on OPTN Committees and the Board of Directors. Members noted that this could particularly lead to over-representation of coastal OPTN members, and dilute the voice of OPOs and transplant programs representing more rural patient populations that cover a larger geographic area.

7. Policy Oversight Committee (POC) Update

The Committee reviewed and provided feedback on the Allocation Based Notification Limits project.

Summary of discussion:

The Vice Chair noted that the POC is comprised of the Vice Chairs of all the OPTN committees. This ensures that the POC's oversight role includes individuals with expertise on the different areas that policy projects may impact. It also provides an opportunity for a committee to identify proposals that other committees are working on that may benefit from cross-committee collaboration.

The POC looks at several factors when reviewing individual projects as well as the entire project portfolio. This includes ensuring the following:

- Alignment with the OPTN goals
- Involvement from the right people at the right time
- Timing and scope of each project

The POC also leads the effort to identify strategic policy priorities. Examples of such projects includes the Tech Tools and Provisional Yes work, as well as the ongoing MOT work.

The POC is currently working to define project benefit and develop a method to rate various attributes. Some attributes discussed have been number of patients affected, level of impact to those patients, and vulnerable populations affected. The goal is to create a more objective measure to evaluate a project's potential impact to the community and considering its sequencing and prioritization.

Another consideration by the POC is how much capacity each committee has to take on more work, but also how much capacity the OPTN staff have to actually implement the planned changes. The capacity to implement changes, in terms of staff hours, has been fairly constant for several years, and the POC has identified a need to increase this capacity. More of our projects involve significant resources to implement, and the work remains important to the community. The POC is currently working with the Finance Committee to request an increase in the available resources for implementing committee work in the next OPTN budget cycle.

The Vice Chair noted that these discussions will have an impact on the OPO Committee work. These impacts include the following:

- Increased discussions about scope earlier in projects
- IT more actively involved in discussing potential options for system solutions earlier in projects
- Some projects may not move as quickly for a while, until we are able to increase the implementation capacity

The Committee did not have any comments or questions.

8. Kidney-Pancreas Allocation Question

The Committee discussed a question presented by SRTR staff regarding the process for allocating a kidney-pancreas according to *OPTN Policy 11.5.A: Kidney-Pancreas Allocation Order*.

Summary of discussion:

Staff noted that the SRTR is currently planning for modeling kidney-pancreas continuous distribution. The simulations used by the SRTR need to implement a predetermined allocation ordering for each donor. Current policy allows for OPO decision-making as outlined in Policy 11.5.A.2.

The SRTR requested input from the Committee about which of the following options were most common at OPOs:

1. **Either A or B** – the OPO makes all required KP shares and then moves to the Kidney, OR the OPO makes all the KP shares/exhausts the KPs and moves to the kidney match run
2. **Percentage of Match Run** – the OPO makes all required KP offers, and then continues to offer KPs to 60% of the remaining match run before switching over
3. **Donor dependent** – the OPO makes all required shares, and if the donor has a low BMI/age (better quality KP donor), the OPO continues to offer all the KPs and exhausts the KP match run before moving to Kidney. Or the OPO makes all required shares, and if the donor has a high BMI/age (lower quality KP donor), the OPO switches over immediately to the kidney match run. (Or vice/versa)

The Committee members agreed that most OPOs exhaust the kidney-pancreas match run before allocating the isolated kidney.

SRTR staff posed another question for the committee members: if a donor has two kidneys available and places one of the kidneys according to the match run, do OPOs execute another match run for the second kidney? Members unanimously agreed that OPOs continue down the original match run.

9. Continuous Distribution of Kidneys & Pancreata Request for Feedback

The Kidney Committee Vice Chair provided an overview of the *Continuous Distribution of Kidneys and Pancreata Request for Feedback* from the Kidney Transplantation Committee and Pancreas Transplantation Committee.

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. One member recommended the Kidney and Pancreas Committees consider transplant center density as an attribute, which could improve allocation efficiency. Another member noted that continuous distribution will need to emphasize placement, transportation, and allocation efficiency in order to make broader sharing possible and practical. A 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.

One 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.

10. Overview of Analytical Hierarchy Process (AHP) for Kidney/Pancreas Continuous Distribution

Staff provided an overview of the AHP exercise in order to prepare to the OPO Committee's "focus group" conference call on March 28, 2022.

Summary of discussion:

Staff presented an overview of the AHP process as well as the rationale for soliciting additional input using focus groups for both OPOs and patients. The Lung Committee developed their continuous distribution proposal using a similar process to gain input from the community. However, when the Lung Committee began reviewing the results they determined that it would be beneficial to future projects if more input was provided from the OPO and patient perspectives.

Staff provided information about what to expect during the focus group meeting. This include the following:

- Complete the AHP exercise
- Be engaged – everyone is needed to be part of the end result.
- Participate in active listening and open dialogue.
- Be solution focused.
- Challenge assumptions and ideas, but not people. Different backgrounds and experiences produce different values.
 - Look for common ground on higher, superordinate goals.
 - If you dissent, speak up and explain the strengths of the alternative.

Next Steps:

- Staff will compile the results of the AHP exercise and public comments after public comment ends on March 23, 2022.
- The report will be distributed to the Committee prior to the March 28, 2022 meeting.

11. Offer Filters Project

Staff provided an overview of the offer filters project and requested feedback.

Summary of discussion:

Staff provided background information on this project. This included the goal of getting to an organ offer acceptance quicker while reducing unwanted organ offers, decreasing cold ischemic time, and increasing organ offer acceptance. Staff noted that voluntary offer filters for kidney was implemented on January 27, 2022.

Staff provided an overview of the Offer Filters Explorer, which allows transplant programs to enter multi-factorial criteria to screen offers more precisely. For example, a kidney program can use filters that combine organ quality (age, higher KDPI) and distance (greater than 250 NM).

Staff reviewed the components of offer filters, which includes the following:

- New electronic organ offer workflow for kidney
- Offer filters explorer
- Offer filters manager
- Offer filters report

Research staff provided usage data on offer filters based on the first five weeks post-implementation. Staff highlighted the following data:

- 119 programs have granted access to the offer filters manager
- 327 personnel across 161 programs have accessed the offer filters explorer
- 58 programs have at least one filter enabled
- 248 total filters are enabled
- 449,711 offers have been bypassed – this is 12.8% of all filters

Staff discussed the opportunity to use the OPO community to increase awareness and usage of offer filters. Committee members were generally receptive to having OPOs help promote offer filters. Several members noted that they have regular meetings with their transplant programs.

Research staff presented some potential “OPO reports” that might assist with those conversions. This included usage data and information about how many transplant programs within the DSA have filters turned on, how many filters, and what kind of filters. Information about the number of offers have been bypassed and the potential impact if recommended filters are turned on.

Recommendations from OPO Committee members included:

- Provide data about transplant hospitals within 250 NM, not just the DSA
- Provide specific recommended filters being used by hospitals in DSAs
- Provide information about discard rates
- Provide information about offers filtered off but transplanted at another program

Upcoming Meetings

- March 28, 2022 – OPO AHP Focus Group (Teleconference)
- April 20, 2022 (Teleconference)

Attendance

- **Committee Members**
 - Kurt Shutterly
 - PJ Geraghty
 - Jennifer Muriett
 - John Stallbaum
 - Malay Shah
 - Valerie Chipman
 - Meg Rogers
 - Erin Halpin
 - Bruce Nicely
 - Chad Ezzell
 - Diane Brockmeier (Virtual)
 - Samantha Endicott (Virtual)
 - Mary Zeker (Virtual)
 - Catherine Kling (Virtual)
 - Larry Suplee (Virtual)
 - Sue McClung (Virtual)
 - Deb Cooper (Virtual)
 - Kevin Koomalsingh (Virtual)
- **HRSA Staff**
 - Raelene Skerda (Virtual)
 - Jim Bowman (Virtual)
- **SRTR Staff**
 - Katie Audette (Virtual)
 - Ajay Israni (Virtual)
 - Josh Pyke (Virtual)
 - Matthew Tabaka (Virtual)
- **UNOS Staff**
 - Robert Hunter
 - Kayla Temple
 - Lauren Mauk
 - Susan Tlusty
 - Lindsay Larkin (Virtual)
 - Ross Walton (Virtual)
 - Katrina Gauntt (Virtual)
 - Matt Cafarella (Virtual)
 - Kelley Poff (Virtual)
 - Kaitlin Swanner (Virtual)
 - James Alcorn (Virtual)
 - Rob McTier (Virtual)
 - Carlos Martinez (Virtual)
 - Nicole Benjamin (Virtual)
- **Other Attendees**
 - Scott Biggins (Virtual)
 - Jim Kim (Virtual)