

Meeting Summary

OPTN Organ Procurement Organization (OPO) Committee Meeting Summary April 22, 2020 Conference Call

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Introduction

The Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 4/22/2020 to discuss the following agenda items:

- 1. Modifications to Released Kidney and Pancreas Allocation
- 2. COVID-19 Discussion
- 3. Deceased Donor Registration (DDR) Project Update
- 4. Policy Oversight Committee Update
- 5. Multi-Organ Policy Review Update

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

1. Modifications to Released Kidney and Pancreas Allocation

UNOS staff provided an overview of the public comments received on this proposal that was distributed for public comment from January 22, 2020 to March 24, 2020.

Summary of discussion:

UNOS staff provided an overview of the post public comment changes made to the policy language.

5.9: Released Organs

- Based on public comment, added requirement that a transplant program releasing an organ "immediately" notify the host OPO or OPTN for further distribution.
- Removed the word "Contractor" in two locations for alignment with other policies.
- Added "or OPTN" to the third sentence in the second paragraph since the OPTN may assist with allocation.

Proposal language: "For kidneys, pancreata, and islets, the host OPO may delegate this responsibility to the OPTN Contractor. For all other organs, the host OPO may delegate this responsibility to the OPTN Contractor or to the OPO serving the candidate transplant program's DSA."

Revised language: "The host OPO may contact the OPTN for assistance allocating the organs. The host OPO may delegate this responsibility to the OPO serving the candidate transplant program's DSA, except in the cases of released kidneys, pancreata, and islets."

The Committee briefly discussed the concern raised by Region 5 and the Membership and Professional Standards Committee (MPSC) regarding the host OPO retaining responsibility for the reallocation of kidneys, kidney-pancreas, pancreas, and islets. However, due to the potential impact on the implementation timeline created by revising the "import backup" process to align with the elimination

of DSAs from allocation, the Committee supported the host OPO retaining responsibility for distribution of released organs.

Policy 8: Allocation of Kidneys

Changes to the proposed language include:

- 8.3 Kidney Allocation Score, *Table 8-4: Proximity Points for Released Kidneys* Changed transplant "program" to "hospital" since the transplant hospital address is used to calculate nautical miles.
- Added "at or" in the table headers for Tables 8-6, 8-7, 8-8, and 8-9 for clarification.

In order to align with other policies, changed "OPTN Contractor" to "OPTN" in the released kidney policy language within the following sections:

- 8.5.H Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%
- 8.5.1 Allocations of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less than 35%
- 8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%
- 8.5.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

Policy 8.8: Allocation of Released Kidneys

- Second bullet Removed redundant language as shown in this strikethrough. Execute a released kidney match run and allocate Allocate the kidney using the released kidney match run in accordance with Tables 8-6, 8-7, 8-8, and 8-9. Also added "or" at the end of the sentence.
- Third bullet Changed "Delegate allocation of the kidney to the OPTN Contractor" to "Contact the OPTN for assistance allocating the kidney"

Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets

Proposed language in *Policies 11.2, 11.4.F, and 11.4.G* will not move forward due to overwhelming public comment concerns about pancreas reallocation. These sections addressed the proximity points for pancreas reallocation as well as the released kidney-pancreas match run.

- 11.4.A: Kidney-Pancreas Allocation Order and 11.4.C: Organ Offer Limits New language added to clarify that these sections do not apply to released organs.
- 11.7 Allocation of Released Kidney-Pancreas, Pancreas or Islets Removes the option to allocate a released kidney-pancreas, pancreas or islets using a "released KP match" and replaces it with the option to allocate the released organs to a potential transplant recipient at the original accepting center. The options to continue down the original match run or contacting the OPTN will remain in the proposed language.

The Committee discussed the public comment recommendations to establish a smaller reallocation circle or center backup for pancreata. Since a smaller reallocation circle would not address the concerns about increased cold ischemia time caused by reallocating the pancreas and could impact the implementation timeline, the Committee agreed that allowing transplant center backup of the pancreas was an acceptable solution. Additionally, the Committee agreed that since pancreata are typically allocated as part of a kidney-pancreas combination, the kidney should also be placed with the pancreas if there is an acceptable candidate at the accepting center. If only the pancreas is placed, then the kidney must be allocated according to the released kidney policy. Committee leadership noted that the leadership of the Kidney and Pancreas Transplantation Committees supported the changes.

The Committee unanimously supported sending the proposed policy language to the Board of Directors for consideration. Committee vote: 17 support, 0 opposed, 0 abstentions.

Transition Plan

The OPTN Final Rule requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised. The Committee briefly discussed the impact of these changes and did not identify any populations that may be treated "less favorably than they would have been treated under the previous policies" if these proposed policies are approved by the Board of Directors. Therefore, the Committee is not submitting any particular transition procedures to the Board of Directors for consideration.

2. COVID-19 Discussion

Summary of discussion:

UNOS staff provided an overview of the actions taken in response to the COVID-19 crisis. These actions included several emergency policy changes that approved by the OPTN Executive Committee on April 3, 2020. These included policies addressing kidney wait time adjustments and data submission requirements. There were also several system changes to allow OPOs to report COVID-19 test result in DonorNet, allow transplant hospitals to enter special COVID-19 refusal codes, and report cause of death related to COVID-19.

UNOS staff also noted that the MPSC would adjust their processes for reviewing policy compliance and the schedule for site surveys. UNOS staff provided an overview of the COVID-19 resources available to members and encouraged members to report any COVID-19 issues using a special questionnaire set up to collect information that will be shared with the Department of Health and Human Services.

Finally, UNOS staff noted that there are ongoing discussions regarding the reporting of eligible donors. They also noted that any change to the current definition would also require changes to the Centers for Medicare and Medicaid Services (CMS) regulations.

3. DDR Review Project Update

Summary of Discussion:

The Committee was provided with an update on this project. This joint Workgroup with the Data Advisory Committee (DAC) continues to meet monthly by teleconference. The Workgroup has completed its review of the clinical information, lifestyle factors, and organ recovery sections of the DDR and will next review the procurement and authorization section. The Workgroup utilizes the DAC's data element standard of review checklist to review each data element, responses, and help documentation to determine if changes are needed.

4. Policy Oversight Committee (POC) Update

The Committee Vice-Chair provided an update on the work of the POC. The POC is currently reviewing a list of project ideas that will be addressed in phases. These focus on efficient matching with the goal in increase organ utilization and include both policy and non-policy projects. These project ideas include:

- Enhanced screening
- Facilitated placement
- Improving pediatric offer acceptance

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¹ 42 CFR §121.8(d).

- Safety net for marginal organs
- Batch offers
- Local backup
- Dynamic offers

A member commented that system changes, specifically DonorNet, should be prioritized in order to provide members with updated tools to adjust to the ongoing changes to allocation policies.

5. Multi-Organ Policy Review Project Update

The Committee Vice-Chair provided an update on this project. The Workgroup has met twice by teleconference to develop a project plan and identify priorities. The Workgroup requested data during its first call and agreed to address the multi-organ transplant (MOT) policies in the following order:

- MOTs involving thoracic organs
- MOTs involving intestines
- MOTs involving kidneys

During its second conference call, the Workgroup briefly discussed the process that OPOs use to allocate multiple organs. A member noted that some OPOs attempt to place cardiothoracic organs first followed by the abdominal organs but also acknowledged the variability in practice across OPOs.

The Workgroup discussed a draft process for allocating heart/liver and lung/liver combinations. This included determining what medical urgency statuses should be used to determine when the "second required organ" must be shared. The Workgroup will continue to refine these recommendations and review data in order to make the best decision.

A member noted the current challenges of trying to decide which list to use. Better guidance is needed to promote practices that are more consistent and provide access to organs for candidates in need of multiple organs.

A member asked about the scenario where more than two organs are required since the policy language only states "the second required organ." Another member noted that his OPO typically tries to place all additional organs with a candidate that needs them although policy clarification would be beneficial.

A member noted that it is challenging to read and understand policy and suggested finding a way to put it all together in one location. Additionally, he recommended using technology to streamline this process.

There were no further comments and the meeting was adjourned.

Upcoming Meetings

- May 27, 2020 (Teleconference)
- June 17, 2020 (Chicago, IL)