

**OPTN Kidney Pancreas (KP) Workgroup  
Meeting Minutes  
May 29, 2019  
Conference Call**

**Nicole Turgeon, MD, FACS, Chair, Kidney Transplantation Committee  
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## **Introduction**

The Kidney Pancreas Workgroup (the Workgroup) met via Citrix GoToTraining teleconference on 05/29/2019 to discuss the following agenda items:

1. Final Rule Considerations in Removing DSA and Region from Kidney and Pancreas Distribution Systems

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

### **1. Final Rule Considerations in Removing DSA and Region from Kidney and Pancreas Distribution Systems**

The Workgroup examined allocation project compliance with the OPTN Final Rule. Members were reminded to keep the Kidney-Pancreas Simulated Allocation Model (KPSAM) and medical experience in mind throughout this process. The Final Rule states that organs not be distributed based on candidate place of residence or listing, except when such distribution is limited by other clauses in the Final Rule. Any options to remove DSA and region that limit distribution must be consistent with the Final Rule clauses that identify acceptable limitations on distribution.

#### Summary of discussion:

A member reminded the Workgroup to use a holistic viewpoint when examining the Final Rule and its clauses in order to get a broad understanding of the justifications for potential allocation policies.

- *(1) Shall be based on sound medical judgement.*

Relevant factors to consider relative to this Final Rule clause include Scientific Registry of Transplant Recipients (SRTR) modeling and experience from the Kidney Allocation System (KAS). A member suggested that the term "sound medical judgment" is vague and subjective. This member appreciated that modeling and prior experience from the KAS is being taken into consideration as she feels the medical community will likely not unanimously agree on the definition of sound medical judgement.

Another member cautioned that the Workgroup should be cautious when selecting a model because if the model selected shows a decrease in the number of transplants, the community may say that the model does not align with clause one. A third member noted that while the Workgroup is unable to change the language within the clauses of the Final Rule, they can give a detailed rationale to defend the decisions that are made.

- *(2) Shall seek to achieve the best use of donated organs.*

Relevant metrics to this Final Rule clause include transplant rates and counts, waitlist mortality, and experience from the KAS. A member noted that the workgroup needs to make sure that certain populations are served, such as highly sensitized patients, pediatric patients, and previous living donors. He emphasized the importance of maximizing organ acceptance, usage, and success. The member said that the community will always look at transplant counts, so the Workgroup should consider those numbers carefully.

A member commented that the dual allocation policy could play a role in achieving the best use of donated organs. A member noted that broader sharing and more air travel will increase cold ischemic time. She suggested examining whether or not this extra ischemic time has negative effects on the quality of the kidneys and transplant outcomes. Another member mentioned that some donor families from region 11 want the organs of their loved ones to stay in the local area.

Recently released data on the changes to lung distribution show an increased rate of discards one year after the implementation of broader sharing for lungs. A member asked if this information would be useful to the Workgroup as they begin to gather suggestions. Another member commented that while this information is important to review, she believes that the Workgroup should not rely on it heavily, as allocation practices for lungs are different from kidneys.

A member asked what kinds of policies allow the maximum utilization rate of organs. He stated that geography is important, but not the only element to consider. Another member replied that a system called facilitated allocation was implemented to increase the utilization rate of pancreata. This system works to place pancreata that may otherwise go unused with aggressive and high acceptance rate hospitals. She suggested that a system like this could be developed for challenging or high Kidney Donor Profile Index (KDPI) kidneys.

- *(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate.*

Workgroup outreach to the community and feedback received during public comment are relevant to this clause of the Final Rule. A member highlighted the understanding that kidney and pancreas are two separate organs that need two separate allocation systems.

- *(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement.*

UNOS staff highlighted certain metrics relevant to this clause of the Final Rule, including discard rates, post-transplant outcomes, impact on cold ischemic time, travel frequency and cost. A member mentioned the importance of selecting the model that will benefit the transplant community the most. The members who represent the Workgroup during regional meetings need to be prepared to discuss the rationale behind the decisions that are made.

A member suggested looking at the differences in access to organs for metropolitan and rural areas as sharing becomes broader. A member commented that this is a situation where

modeling is limited and expertise may have to guide decisions. This member gave Alaska, Hawaii, and Puerto Rico as examples of locations where experience will need to play a larger role.

- *(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a) (1) - (5) of this section.*

The Workgroup reviewed the importance of removing Donor Service Area (DSA) and region from policy in order to increase equity and access. A member commented that she felt that the clauses of the Final Rule were unbalanced and that clause eight was given the most priority. UNOS staff noted that the Final Rule should be looked at in a holistic manner where all the clauses are considered.

A member cautioned that they did not believe broader sharing would lead to an increase in transplant rates. Another member reminded the Workgroup that the original modeling that showed a decrease in the rate of transplants was not received well by the community. This member asked how an increase in equity can result if the rate of transplants decreases. A member replied that medical and ethical expertise will need to be substantive. A member asked how the improvement of equity would be assessed. Another member emphasized the importance of looking at waiting time or dialysis time. A member said that SRTR will provide data on vulnerable populations and socioeconomic status. This data could contribute to considerations surrounding equity.

#### Next steps:

SRTR modeling report is due to be received mid-June. UNOS staff will forward the report to Workgroup members upon its arrival. The OPTN will then hold full Kidney and Pancreas Committee calls where SRTR will present the modeling request.

#### **Upcoming Meetings**

- June 17, 2019- Full OPTN Kidney Committee Call (Teleconference)
- June 19, 2019- Full OPTN Pancreas Committee Call (Teleconference)
- June 25, 2019- Separate OPTN Pancreas and Kidney Committee meetings in Baltimore, MD (In-Person)
- June 26, 2019- KP Workgroup call (Teleconference)
- June 27-July 1- Webinars for OPTN members to provide feedback (Teleconference)

#### **Attendance**

- **KP Workgroup Members**
  - Sharon Bartosh
  - Vincent Casingal
  - Donna Croezen

- Alejandro Diez
- Silke Niederhaus
- Martha Pavlakis
- Nicole Turgeon
- Andrew Weiss
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Joyce Hager
- **SRTR Staff**
  - Sally Gustafson
  - Bryn Thompson
- **UNOS Staff**
  - Nicole Benjamin
  - Scott Castro
  - Beth Coe
  - Abby Fox
  - Lindsay Larkin
  - Kelley Poff
  - Tina Rhodes
  - Leah Slife
  - Kiana Stewart
  - Read Urban
  - Ross Walton
  - Amber Wilk