OPTN/UNOS Pediatric Transplantation Committee
Meeting Minutes
September 20, 2017
Conference Call

William Mahle, M.D., Chair
George Mazariegos, M.D., Vice Chair

Introduction

The Pediatric Transplantation Committee met via teleconference on September 20, 2017 to discuss the following agenda items:

1. Improving En-bloc Kidney Allocation II
2. Broaden Pancreas Allocation Across Compatible ABO Blood Types

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

1. Improving En-bloc Kidney Allocation II

The Chair of the OPTN/UNOS Kidney Transplantation Committee shared a presentation regarding modifications to a proposal to improve en-bloc kidney allocation.

Summary of discussion:

In the spring of 2017, the Kidney Committee developed a proposal to improve en-bloc kidney allocation. The goal of this proposal was to provide direction for OPOs when to allocate en-bloc kidneys. The Pediatric Committee agreed with the premise that donor weight was appropriate to drive en-bloc kidney allocation, supported an increase the upper limit of weight range to 20 kg for mandatory en-bloc allocation, and the removal of the "intermediate" weight range (15-25 kg) to allow OPOs the choice to allocate either as en-bloc or single kidney.

In June 2017, the OPTN/UNOS Board of Directors did not approve the proposal and asked the Kidney Committee to consider modifications. Specifically, feedback was shared that the weight threshold of 20 kilograms was too high.

Nicole Turgeon, M.D., Chair of the OPTN/UNOS Kidney Transplantation Committee, presented an update on the modifications to the en-bloc proposal. The problems at hand remains:

- No OPTN policy on allocating en bloc kidneys
- DonorNet® overestimates KDPI score for en bloc kidneys, potentially screening medically suitable candidates off the match run
- DonorNet® has communication limitations

The goals of the proposal continue to be:

- Mandatory en-bloc allocation based on donor weight
- Allocate en bloc kidneys based on KDPI 0-20% (Sequence A)
- Mask KDPI score in en-bloc kidney allocation
- Centers must report to UNOS that they are willing to accept en-bloc kidneys in order to receive en-bloc offers
- Kidneys allocated en-bloc can be split at surgeon's discretion

Dr. Turgeon stated the change in the proposal included requiring kidneys from donors less than 18 kg to be allocated as en-bloc. The Kidney Committee reviewed data on deceased donor kidney transplants and noted that data showed that kidneys from donors 19 kg or more are

predominantly single transplants rather than en-bloc. The Kidney Committee believed lowering the weight range below 18 kilograms would disadvantage centers that transplant these kidneys en-bloc. The Kidney Committee also intends to "mask" the Kidney Donor Profile index (KDPI) for en-bloc kidneys to preserve access for pediatric candidates. Members of the Kidney Committee were concerns that the KDPI for these pediatric donors is inconsistent with the quality of the organs, thus blunting a transplant team's tendency to consider these kidneys for pediatric candidates.

Both the original proposal and the current proposal would allow surgeons to split en-bloc pairs of kidneys, should the surgeon decide they are appropriate for single transplant. By leaving the weight threshold at 18 kilograms, this would continue to allow discretion at those Transplant programs that are doing en-bloc transplants with good outcomes. Further, it would also allow the option to split the kidneys if the transplant team deemed appropriate.

Dr. Turgeon reported that many members of the community and the Board expressed concern about transporting the "second kidney" and risking discard with added cold ischemic time, and stated a preference for this policy to allow surgeons to automatically keep the second kidney in a split pair at their center. The Kidney Committee appreciated this feedback and discussed these concerns at length. The proposal states that the receiving transplant program must *either* transplant one kidney into the originally designated recipient and release the other kidney to be allocated according to Policy 5.9, or release both kidneys to be allocated according to Policy 5.9.

At the conclusion of the presentation, Dr. Turgeon summarized that the expected impact on pediatric kidney transplant candidates would be small in light of the low case volume noted in OPTN data in the past 10 years.

The Chair thanked Dr. Turgeon for the presentation and opened the floor for questions. Members of the Pediatric Committee discussed several points, including:

- Age of transplant recipients: Committee members clarified that most of the recipients of en-bloc kidneys were indeed adults. Dr. Turgeon showed the pediatric case volume of en-bloc and small single kidneys (47 transplants over 10 years) both pre and post-KAS.

- Risk adjustment for en-bloc and small single kidney transplants: The paper cited by Maluf and colleagues in the proposal showed equivalent outcomes of single versus en-bloc kidneys. There are some in the surgical community that are concerned about nonequivalent outcomes. Would programs that transplant these kidneys put themselves at "flagging risk" [graft and patient survival outcomes]? Dr. Turgeon responded, the paper noted that programs that had higher case volume and were technically sound, had good one year graft survival with kidneys from small pediatric donors. She felt the data supports that recipients will have better outcomes in the setting of both small-single kidney and en-bloc kidney transplants at these higher volume transplant programs. She also feels comfortable after talking with Scientific Registry of Transplant Recipients (SRTR) colleagues that the outcomes analysis will include the proper risk adjustment.

The potential to include an "incentive" to split en-bloc kidneys: A small number of Committee members felt there was an opportunity to modify the proposal such that surgeons could be incentivized to split en-bloc kidneys. Such a practice exists in liver transplantation; a liver allocated to a pediatric recipient can be split (based on the clinical decision-making of the transplant team) and two pediatric candidates can be transplanted. There appeared to be an opportunity to effect a policy change by giving the accepting surgeon the option to keep the "second kidney", rather than reallocate the kidney. Dr. Turgeon responded the Kidney

Committee requested additional data to explore this scenario. The data noted that most of the "second kidneys" in this scenario do stay at the program that accepted the en-bloc pair. Further, the data noted that if the "second kidney" does not remain at the same program, it is far more likely that the "second kidney" remains within the Donation Service Area (DSA). Dr. Turgeon added that the proposal does not take away the accepting surgeon's discretion to split the two organs. However, the proposal does not alter OPTN Policy 5.9 requiring the "second kidney" to be allocated based on the match run list.

One Committee member commented that the OPTN data on the topic had gaps. Dr. Turgeon acknowledged that OPTN data on en-bloc and small single kidney transplants is lacking. The Kidney Committee felt this lack of available data justified the need for a policy change that would allow the collection of such data. The Kidney Committee feels this proposal is a "good start", and is neither an incentive nor disincentive to split en-bloc kidneys. Further, the hope is this proposal will incentivize recovering small en-bloc kidneys that have not historically been recovered for transplantation. She reminded the Committee of the low frequency these kidneys are utilized in pediatric candidates due to the potential for vascular complications. She feels the proposal's "masking" of the KDPI for en-bloc kidneys will preserve access for pediatric candidates. The Kidney Committee will have on-going post implementation monitoring to assess the effectiveness of the policy change.

> Dr. Turgeon summarized that comments from members of the Committee shared during the call regarding an incentive to split en-bloc kidneys represent a good "future state". The Kidney Committee believes the current proposal is a fair and inclusive "starting point". The intent of this policy was not to incentive splitting en-bloc kidneys. Rather, the intent was to provide direction to OPOs to allocate en-bloc kidneys and to continue to allow splitting en-bloc kidneys under the clinical judgement of the transplant team. She believes that the position of not "incentivizing" splitting in the proposal would effectively "disincentivize" splitting, is not accurate. Dr. Turgeon commented, she feels it is important to give a subsequent potential recipient on a match run list the opportunity to receive a transplant, regardless whether the potential recipient as at the same program as the index potential recipient. By creating an incentive such as described, it would overly advantage those transplant programs performing these small solidary kidney transplants by separating en-bloc pairs. She felt that was challenging to effectively move clinical practice when there is the absence of data to support moving in that direction yet.

The Chair concluded the discussion on the proposal and thanked Dr. Turgeon for her presentation. UNOS staff then asked for a vote from the Committee whether they support the proposal as written. The proposal was supported (Yes – 10, No – 2, Abstain – 0).

Next steps:

- UNOS staff will prepare a draft response from the Committee and submit to the Chair/Vice Chair for review. Thereafter, the Committee's response will be posted on the OPTN website for the sponsoring committee to consider post-public comment.

2. Broaden Pancreas Allocation Across Compatible ABO Blood Types

The Chair of the OPTN/UNOS Pancreas Transplantation Committee shared a presentation regarding modifications to a proposal to Broaden Pancreas Allocation Across Compatible ABO Blood Types.

Summary of discussion:

Jon Odorico, M.D., Chair of the OPTN/UNOS Pancreas Transplantation Committee, presented a proposal to broaden pancreas allocation in the U.S. The problems at hand include:

- The number of pancreas transplants has declined significantly since early 2000s, even while outcomes have improved.
- Current blood type restrictions prevent compatible transplants from occurring
- These restrictions could lead to pancreata being discarded and fewer transplants

The Pancreas Committee seeks to increase pancreas transplantation and reduce discarded pancreata by modifying the allocation system to allow clinically compatible transplants. The goals of the proposal include:

- Prioritize high-cPRA ABO-identical candidates, then high-cPRA compatible candidates, then all identical, then all compatible
- Allow A, non-A1 and AB, non-A1B compatible pancreas or kidney-pancreas to B candidates
- Allow B pancreas or kidney-pancreas to B or AB candidates
- Remove restrictions on blood type O compatibility:
- A, B or AB candidates need zero antigen mismatch (0-ABDR) + cPRA ≥80 to receive O pancreas or kidney-pancreas in current policy

The Pancreas Committee engaged the SRTR for modeling to assess the impact of several scenarios. The proposal reflects the simulation that projected a net gain in pancreas transplants. The Committee acknowledges a reduction of kidney alone transplants in the modeling and believes it is offset by the beneficial net increase in kidney/pancreas transplants and reduced discard rate for pancreata. The projected reduction of kidney-alone is extremely small compared to the number of deceased donor kidney alone transplants (there were 13431 in 2016, or a projected decrease of .7%). By contrast, there were only 798 kidney/pancreas transplants in 2016, so an increase of 143 would be an increase of 17.9%.

At the conclusion of the discussion, the Chair thanked Dr. Odorico for the presentation and opened the floor for discussion. While members were glad to see there was no net-negative impact on pediatric kidney alone candidates nationally, several members commented that regional and DSA-level data would be helpful to assess geographic impact. There is concern specifically in Region 4 that pediatric solitary kidney candidates are disadvantaged by simultaneous pancreas/kidney (SPK) transplants. Committee members encouraged robust post-implementation monitoring to assess for impact on pediatric transplants.

Following the discussion, UNOS staff asked for a vote from the Committee whether they support the proposal as written. The proposal was supported (Yes – 8, No – 2, Abstain – 2). However, members of the Committee verbalized their desire to look at additional data from the Pancreas Committee and SRTR. The Chair asked members to submit their requests and questions to leadership and UNOS staff. A representative of the Pancreas Committee is invited back to respond to these outstanding concerns.

<u>Next steps:</u>

- UNOS staff will prepare a draft response from the Committee and submit to the Chair/Vice Chair for review. Thereafter, the Committee's response will be posted on the OPTN website for the sponsoring committee to consider post-public comment.

With no further time in the meeting for discussion, the UNOS staff presentation on the Pediatric Supplement to the Benchmark Report will be tabled for a future call/meeting. The call was then adjourned.

Upcoming Meeting

- October 12, 2017 9-3 Central (Chicago, IL)

- November 15, 2017 4-5 PM Eastern (full committee conference call)
- December 20, 2017 4-5 PM Eastern (full committee conference call)
- January 17, 2018 4-5 PM Eastern (full committee conference call)
- February 21, 2018 4-5 PM Eastern (full committee conference call)
- March 21, 2018 4-5 PM Eastern (full committee conference call)
- April 12, 2018 9-3 Central (Chicago, IL)
- May 16, 2018 4-5 PM Eastern (full committee conference call)
- June 20, 2018 4-5 PM Eastern (full committee conference call)

Attendance

- **Committee Members**
  - William Mahle, M.D., Chair
  - George Mazariegos, M.D., Vice-Chair
  - Kashayar Vakili, M.D.
  - Rachael Ryan, RN, B.S.N., CCTC
  - Amira Al-Uzri, M.D.
  - Arika Hoffman, M.D.
  - Kishore Iyer, M.B.B.S., FRCS, FACS
  - Sharon Bartosh, M.D.
  - Evelyn Hsu, M.D.
  - Melissa McQueen
  - Melissa Nugent, RN, B.S.N. CCRN, CCTC
  - John Renz, M.D.
- **HRSA Representatives**
  - Marilyn Levy
  - James Bowman, M.D.
- **SRTR Staff**
  - Katherine Audette
- **OPTN/UNOS Staff**
  - Christopher L. Wholley, M.S.A.
  - Amanda Robinson
  - Chelsea Haynes
  - Chad Southward
  - Melinda Woodbury
  - Amber Wilk
  - Kimberli Combs
  - Abigail Fox
- **Other Attendees**
  - Nicole Turgeon, M.D., Chair – OPTN/UNOS Kidney Transplantation Committee
  - Jon Odorico, M.D., Chair – OPTN/UNOS Pancreas Transplantation Committee