

OPTN/UNOS Kidney Transplantation Committee
Meeting Summary
November 21, 2016
Conference Call

Mark Aeder, MD, FACS Chair
Nicole Turgeon, MD, FACS, Vice Chair

Discussions of the full committee on Nov. 21, 2016 are summarized below. All committee meeting summaries are available at <https://optn.transplant.hrsa.gov>.

Committee Projects

1. Double Kidney Allocation Project

The Committee Chair presented an update on the Double Kidney and En Bloc Allocation projects.

En bloc

The En Bloc Work Group's proposal will go to Public Comment in January 2017. The En Bloc Work Group will consider/incorporate public feedback as needed in March and the full Committee will review and vote to send to Board in June.

Double Kidney

The Work Group last met on November 18th to review the comments from the Kidney Committee's October in-person meeting. No clear consensus on policy has been reached within the Work Group itself, the Committee and UNOS internal staff. Support for two general concepts has surfaced: a criteria-based placement scheme and an allocation-based scheme.

In the absence of consensus, the Work Group proposed putting forth a concept paper describing both of the proposed schemes for public review and comment in parallel with the official spring Public Comment period. The paper would be posted on the OPTN Web site to allow for any member of the public to review and comment on the proposed concepts. A concept paper is a UNOS staff work product that does not require the Kidney Committee's approval for publication. The Double Kidney Work Group would then be able to review community feedback and build a proposed policy in time for the fall 2017 Public Comment period. Putting forth a concept paper does not impact the Work Group's current timeline.

One member commented that the concept paper will help build consensus on the front end of the policy development process. Another member commented that the reduction of discards of these kidneys is one of the primary goals of the project. The policy developed must be nimble - so often, information comes post-recovery. Many in the group were supportive of allocating duals as early as possible along a sequence.

The Chair requested that the individual members of the Kidney Committee consider the concepts proposed and send comments, concerns or ideas to the Committee Liaison for consideration by the Work Group.

Other Significant Items

2. “2015 Transplant Activity Report” - OPTN Ad Hoc International Relations Committee

The Committee received a presentation from Susan Gunderson, Chair of the OPTN Ad Hoc International Relations Committee on the 2015 Transplant Activity Report.

The IRC Chair presented the 2015 Transplant Activity Report with the intention of sharing some of the Committee's preliminary analyses and to gather feedback from members of the Kidney Committee on questions that may arise.

In 2012, there was a Board Policy change to modify the citizenship categories upon which data were collected. The previous did not properly categorize why non-US citizens were living in the US and were also unable to identify individuals entering the US specifically for a transplant. The new categories of data collection, implemented in 2012, are:

- US Citizens
- Non-US citizens/US residents
- Non-citizen, non-residents in the US for other reasons
- Non-citizen, non-residents in the US for purpose of transplant

The policy change also mandated an annual report on the activities related to registration and transplantation of non-US Citizen/non-US residents.

Country of residence is now also collected information.

The goal of these policy changes was to enhance transparency in listing for these candidates coming to the US specifically for this procedure.

The IRC must now publish the annual report of Non-Citizen/Non-Resident (NCNR) registrations per policy 17.1.C. The IRC has not come to any conclusions about how to ask questions of transplant hospitals, but rather would ask the relevant Committees on how to review this information. Thus, the IRC asks the Kidney Committee today to share what information is meaningful, what questions arise when reviewing the data, and what additional information is desired.

In 2015, 321 (0.6%) non-US residents are in the US for the specific purpose of transplantation. 425 (0.7%) of non-US residents are here for other reasons. 0.6% of transplants for non-US residents in the US specifically for transplant were from deceased donors, and 0.8% of deceased donor transplants went to non-US residents in the US for reasons other than transplant. The vast majority (76%) of transplant hospitals do not list NCNR candidates. Only 6.5% (54 total) of programs listed NCNR candidates.

There has been a small increase in the number of kidney transplants to NCNR candidates, from 69 in 2013 to 109 in 2015. Overall, kidneys remain a small percentage of total NCNR transplants. DD kidney transplants in NCNR candidates rose from 9 in 2013 to 25 in 2015.

Saudi Arabia and Kuwait were the two largest non-US contributors to Kidney Waitlist registrations from April 2015-May 2016 with 15 registrants each. Regions 3 and 7 had the highest number of kidney transplants performed in this same time period, with 5 and 6 respectively.

In an analysis of waiting time and mortality, the IRC was unable to identify any significant differences between NCNR candidates and all others due to limited availability of data.

After reviewing all data available from the 3 prior years, the IRC has made the following general observations:

- No difference between % of non-US residents listed for transplant and % of non-US residents receiving transplant
- Absolute number of WL additions and deceased donor transplants remains very low, however numbers and % have increased
- Two countries of residence comprise the highest number of kidney candidates and transplants: Kuwait and Saudi Arabia
- Region 3 had the greatest number of registrations and transplants for NCNR Travel for Transplant

After the presentation, the IRC Chair asked the Kidney Committee to consider the following questions:

1. The goal of Policy 17.1 is to ensure transparency with regard to the transplantation of international patients who travel to the US for the purpose of transplant. It is expressly not the purpose of the policy to prohibit such transplants. Should additional goals be considered?
2. What does the data tell us about whether there is a concern or problem? In the absence of policy guidance, how should thresholds for review of program specific results be developed?
3. What does appropriate report distribution look like – is posting with the UNOS Board agenda packet sufficient?
4. UNOS endorsed the principles of the Declaration of Istanbul on Organ Trafficking and Transplant tourism in 2009, including the principles of transparency and self-sufficiency – how should the analysis of NCNR reflect endorsement of these principles?

The first review was trying to understand the individuals that come to the US specifically for transplant. There is a challenge to identify and categorize the large numbers of individuals who are undocumented, in the US for a work visa, etc. The Kidney Committee Chair commented that a breakdown of data for these types of categories would be helpful.

The Vice Chair commented that the actual numbers of NCNR candidates are quite small. Within those small numbers, the representation seems to be lopsided in one or two regions. Part of the exercise was to see if certain hospitals in these regions were in agreement with this assessment and/or saw a negative impact on the hospital or region itself. Are these additional candidates influencing the hospital's ability to be self-sufficient? Does this activity impact their ability to serve the region's population? So far, data does not demonstrate this.

The Chair adjourned the meeting.

Upcoming Meetings

- Dec. 19, 2016, 5:00PM EST
- Jan. 9, 2016, 12:00PM EST
- Feb. 27, 2016 5:00PM EST