Summary
Histocompatibility Committee Meeting
December 5, 2012
2:00-4:00pm ET
Conference Call

Participants:

- Committee: Lee Ann Baxter-Lowe PhD,D (ABHI), Dolly Tyan PhD, D(ABHI), Nancy Reinsmoen PhD, D(ABHI), Neng Yu MD, Julie Houp, Robert Bray PhD, D (ABHI), Cathi Murphey PhD, Ellen Klohe PhD, Sara Dionne, PhD, A. Bradley Eisenbrey MD PhD, David Kiger CHS CHT, Luis Campos MD, Ba Lin MS, MPH
- OPTN: Gena Boyle, Anna Kucheryavaya, Cheryl Hall, James Alcorn, Ciara Samana, Elizabeth Miller
- SRTR: Sally Gustafson, Susan Leppke

Summary:

The OPTN/UNOS Histocompatibility Committee met via Live Meeting on December 5, 2012 to review the proposal to substantially revise the kidney allocation system recently released by the Kidney Transplantation Committee (Kidney Committee) and to vote on recommendations from the Equivalency Table Update Subcommittee.

New Kidney Allocation Proposal

Sally Gustafson, SRTR staff, presented simulated results requested by the Histocompatibility Committee in August. John Friedewald, MD (Chair of the Kidney Committee) and Nancy Reinsmoen, PhD, ABHI presented the proposal on behalf of the Kidney Committee. The Histocompatibility Committee voted in favor (1-Support, 10-Support with Amendment, and 0-Oppose and 1-No Opinion) of supporting the proposal with the addition of two amendments:

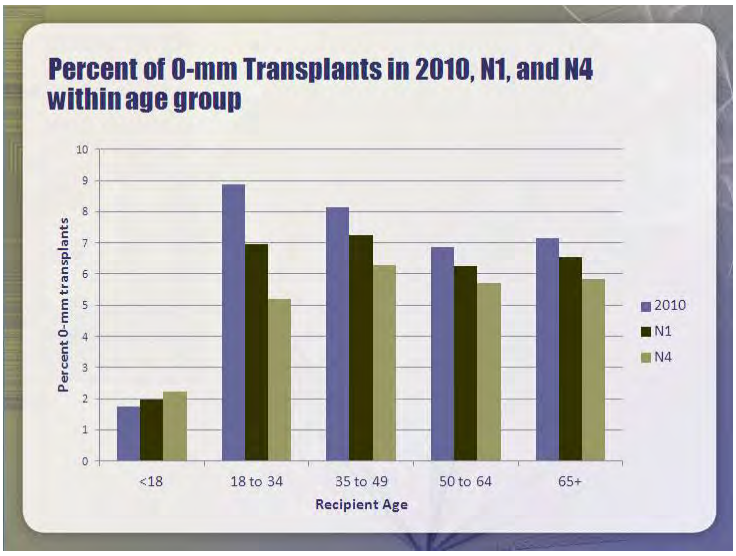
1. Creating a ranking system that prioritizes zero-HLA mismatch offers over non-zero mismatch offers within each category of very highly sensitized patients (CPRA scores with 100%, 99% and 98%).

2. A future policy proposal to allow variances in one or more regions of the country to allow candidates who undergo desensitization to maintain their initial or higher CPRA score (prior to desensitization) for six months after desensitization.

In August, the Histocompatibility Committee requested data for 2010 and simulated (N1, N4) zero-HLA mismatched kidney transplants stratified by age group, recipient sensitization level, and retransplant status. Staff from the SRTR presented the simulated results.

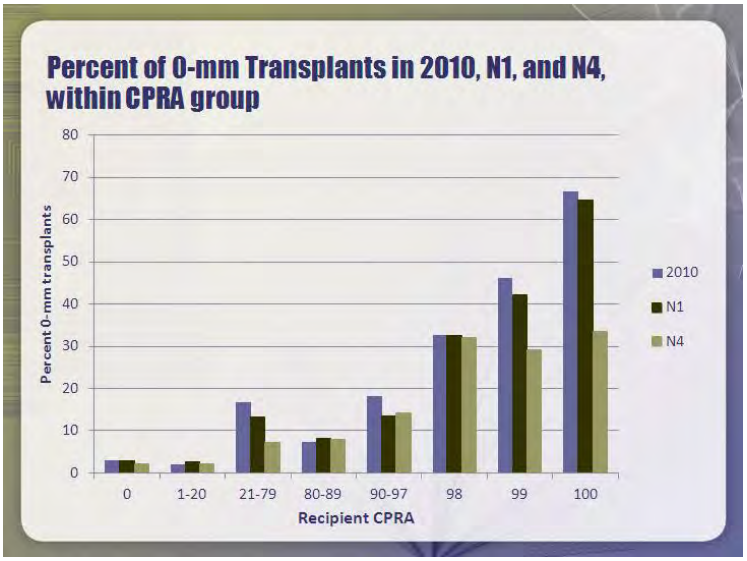
Several members of the Committee were concerned that the simulated results (shown below) show a decrease in the percentage of zero-HLA mismatched kidney transplants for candidates in age groups 18-34 and 35-49. Members of the Committee explained that it is especially important for candidates in these age groups to receive zero-HLA mismatched transplants in

order to prolong the life of the graft and prevent future sensitization for individuals who are likely to need an additional transplant later in life.

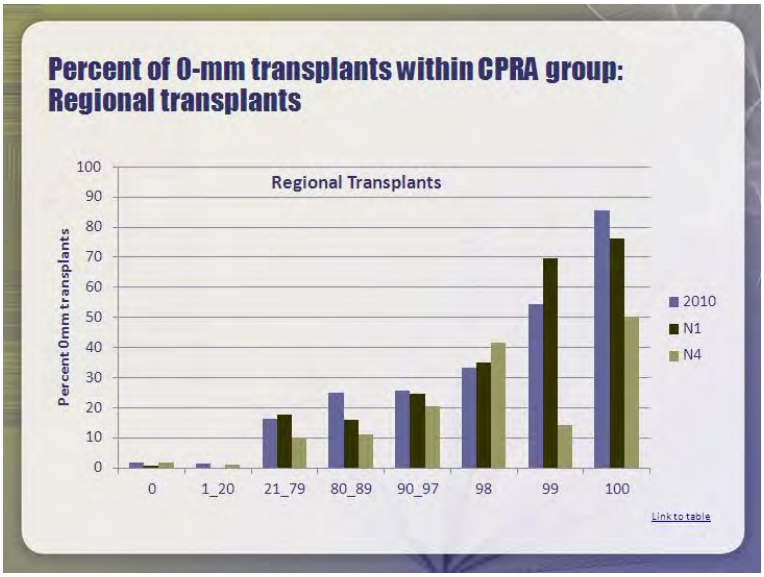


Members of the Committee asked Dr. Friedewald whether the Kidney Committee has discussed the proposal's effects on these age groups. Dr. Friedewald responded that the Kidney Committee has discussed this and they suspect that the reason for the decrease is likely the priority given to highly sensitized patients (those with CPRA scores greater than or equal to 98%). Dr. Friedewald added that there are some in the transplant community who have questioned this prioritization of highly sensitized patients, arguing that prioritizing transplants to patients who typically have poorer outcomes goes against the Kidney Committee's efforts to increase longevity of grafts. However, the Kidney Committee tried to take a balanced approach in order to increase access for highly sensitized patients.

Members of the Committee were also concerned that the simulation results show a decrease in the percentage of zero-HLA mismatched transplants allocated for candidates with CPRA scores of 99% and 100% (see below). Dr. Friedewald responded that highly sensitized patients are actually exposed to a larger share of kidneys in the new allocation system and have a higher transplant rate overall.

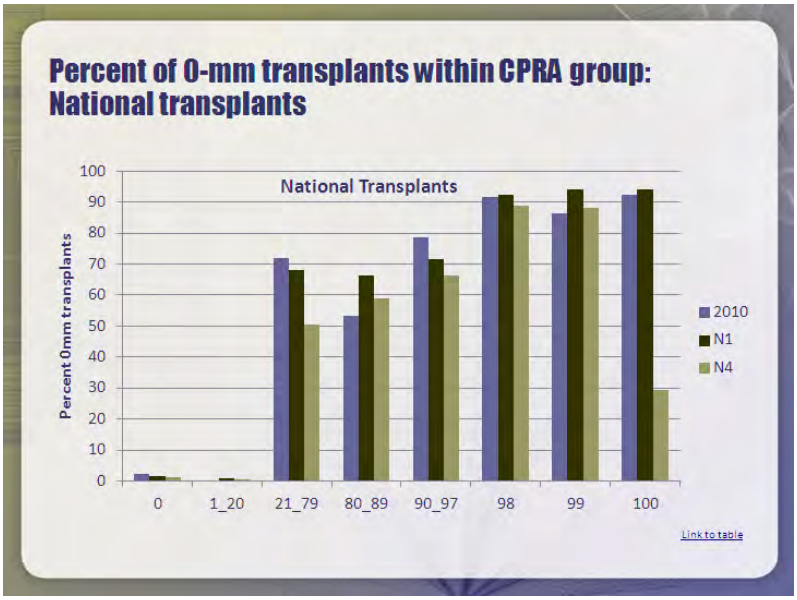


Similarly, members of the Histocompatibility Committee were concerned that the simulation showing the percentage of zero-HLA mismatched transplants by local, regional and national sharing showed a marked decrease from 2010 to N4 in the percentage of zero-HLA mismatched transplants regionally for candidates with CPRA scores of 99% and 100% (see below). SRTR staff responded that the chart shows percentages of zero-HLA mismatched transplants within the overall number of transplants for these groups and that the number of transplants is higher in each category. Members of the committee asked to see the denominators for each of these categories and the SRTR agreed to provide them after the meeting.



The simulation also showed a large decrease in the percentage of zero-HLA mismatched transplants nationally for candidates with a CPRA score of 100%. Several of the committee members were concerned about this decrease. Dr. Friedewald responded that a solution could be to prioritize zero-HLA mismatched kidneys within each category of highly sensitized

candidates (100%, 99%, 98%) by creating a ranking system where zero mismatched organs are allocated first in the highest group and then non-zero mismatched organs in that same group. Members of the committee agreed with this approach.



Dr. Reinsmoen presented the overall Kidney Committee proposal to the committee. Members of the Committee asked Dr. Friedewald whether or not the Kidney Committee would consider addressing the issue of desensitization protocols in the new allocation proposal. The committee has previously discussed allowing candidates who undergo desensitization to maintain their points allocated for CPRA prior to desensitization for six months following desensitization so that they would maintain allocation priority while being exposed to a broader donor pool. Dr. Friedewald responded that this might best be handled by a future proposal to create a variance in one or more regions to gain data on the effectiveness of such a change. Members of the committee agreed with this approach.

Dr. Reinsmoen also informed the committee that the Kidney Committee has received a considerable amount of feedback on the need for mechanisms to record DPB and DQA antigens in DonorNet. The Histocompatibility Committee is releasing a proposal in Spring 2013 to add optional fields in DonorNet and Waitlist to record DQA and DPB antigens for donors and as unacceptable antigens for candidates. In the meantime, however, members of the committee suggested conducting an education campaign to alert the community that antigens not currently programmed as optional fields can be recorded by attaching a file in DonorNet. The committee agreed that this is the best approach until the future committee proposal is approved and programmed.

Equivalency Table Update Subcommittee Recommendations

Julie Houp presented recommendations on behalf of the Equivalency Table Update Subcommittee ("the subcommittee"). The subcommittee is recommending substantial changes to the Equivalency Tables currently found in Appendix 3A.

Ms. Houp explained that the first subcommittee recommendation is to update the format of the tables to a make them more 'user friendly' and easier to understand. She then reminded the committee of the purpose and significance of each of the tables. The first table is used for determining the level of match between a candidate and a donor. In kidney and pancreas allocation, candidates with zero-HLA-A, B, and DR mismatched transplants are given priority. The second table lists unacceptable antigen equivalents used when screening off candidates from a match run for a donor during allocation. This table also has implications for a candidate's Calculated Panel Reactive Antibody (CPRA) score, which also affects priority for kidney and pancreas transplant allocation priority.

The subcommittee presented six recommended changes to the first table, all of which were approved. The committee then voted to add two additional changes to the first table. Since the first table lists donor HLA and OPTN policy currently requires all deceased kidney donors to be typed by molecular methods, the subcommittee is recommending deleting several broad antigens that are no longer equivalent. Several members of the committee voiced concern over these recommendations, wondering how the changes would affect candidates who were typed by serology and have broad antigens currently listed on the waiting list. Specifically, members were concerned that these changes would mean that certain candidates will no longer have access to a zero-HLA mismatch transplant. Ms. Houp responded that the subcommittee considered this in their recommendation and ultimately predicted that transplant programs will respond to the change by retyping candidates using molecular means. Several members of the subcommittee advocated for a UNOS education tool that would help transplant programs and laboratories understand that candidates typed by serology may be significantly disadvantaged by the current and future version of these tables.

One committee member inquired whether the committee could approve these changes contingent upon future policy proposals to 1)require candidates with broad antigens listed on the waiting list to be retyped using molecular typing; and/or 2)create a UNOS 'report card' to be released annually that would communicate to centers that their patients have broad antigens listed. UNOS policy staff explained that those actions would need to be accomplished through a separate policy proposal. The committee voted to unanimously accept the recommendations to the first tables.

Ms. Houp then presented the recommended changes to the second table and policy language listing unacceptable antigens used for CPRA calculation only. The subcommittee recommended a substantial number of changes to the second table that reflect current typing practice. In addition, they recommended adding language that was previously deleted by the committee to include some unacceptable antigens as equivalent for the purpose of CPRA calculation only. The Committee unanimously adopted these recommendations as well.

The Committee adjourned at 4:00pm ET. The next meeting will be held by conference call on January 3, 2013 at 12:00pm ET.