OPTN/UNOS Thoracic Organ Transplantation Committee
Meeting Minutes
January 16, 2018
Conference Call

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Introduction

The OPTN/UNOS Thoracic Organ Transplantation Committee (the Committee) met via Citrix GoToTraining teleconference on January 16, 2018 to discuss the following agenda items:

1. Thoracic Simulation Allocation Model (TSAM) of Broader Distribution of Deceased Donor Lungs

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

1. TSAM of Broader Distribution of Deceased Donor Lungs

The Committee requested the Scientific Registry of Transplant Recipients (SRTR) perform modeling to analyze the effect of distributing lungs first to all eligible candidates in the donation service area (DSA) vs. distributing lungs first to all eligible candidates within a 250 nautical mile (NM) circle around the donor hospital vs. distributing lungs first to all candidates within a 500 NM circle around the donor hospital. The SRTR presented the results of its analysis to the Committee.

Data summary:

- Population & Methods

The cohort includes all candidates, donors and recipients between July 1, 2009 and June 30, 2011. This is the most recent cohort available for the TSAM as of the date of the request. The TSAM simulates match runs according to the rules provided by the committee. As mentioned above, the match runs simulate distributing first to the DSA vs. distributing first to a 250 NM circle vs. distributing first to a 500 NM circle. The TSAM runs each set of rules 10 times, and the graphs of the results show the average, minimum, and maximum results across the 10 simulations for each of the three distribution scenarios. The SRTR does not provide statistical significance testing because the data are not independent and do not allow for it.

- Overall transplant rates and counts
    - The 250 NM simulation and DSA simulation are virtually identical
    - The average number of transplants is pretty similar at 250 NM compared to the DSA, and increases a bit in the 500 NM simulation, but the transplant rate decreases
        - The transplant rate is the sum of the number of events over the sum of observed time, so if there are people spending more time on the list you might see more transplants but lower rates
- Overall waitlist mortality rates and counts
    - The 250 NM simulation overlaps with DSA simulation, though the average number of deaths declines a bit
    - In the 500 NM simulation the difference becomes more definitive, as the minimum and maximum limits of the death counts and rates do not overlap with the DSA or 250 NM simulations. The number of waitlist deaths and the rate of waitlist deaths is lower.
- Overall one-year post-transplant mortality rates and counts

    - All of the simulations for each of the three distribution scenarios are similar and results overlap
    - In the counts for 500 NM simulation, the average number of deaths increased, but so did the average number of transplants. This is because more people are at risk for post-transplant deaths because there are more people transplanted under the 500 NM simulation.
- Transplant rates and counts by diagnosis
    - In the 250 and 500 NM simulation, the transplant rates and counts declined for diagnosis group A, trended up for diagnosis groups B and C but simulation ranges overlapped
    - In the 500 NM simulation, the transplant rates and counts increased for diagnosis group D when compared to the 250 NM and DSA simulations
        - These are expected outcomes because candidates with lower LAS scores will wait longer and have less access to transplant and have fewer transplants. Candidates in diagnosis group D typically have higher LAS scores, so it is expected that group D's transplant rates would increase with broader distribution.
    - It is important to acknowledge the effects of the 2015 changes to the LAS calculation are not reflected in the cohort included in the TSAM. The 2015 LAS changes generally impacted candidates in diagnosis group B by increasing their LAS scores, and candidates in diagnosis group D by slightly decreasing their LAS scores.
        - If the TSAM used an updated cohort that reflected the 2015 LAS changes, it is possible that group B candidates may have modeled higher transplant rates and group D candidates modeled lower transplant rates than currently displayed between distances.
- Waitlist mortality rates and count by diagnosis
    - In the 250 NM simulation, waitlist mortality rates are similar for all diagnosis groups compared to the DSA simulation. Some have points estimates that might decline slightly, but the ranges overlap.
    - In the 500 NM simulation, point estimates for waitlist mortality declined in all diagnosis groups, but most considerably in group D. The counts of waitlist deaths declined for candidates in diagnosis groups C and D, while counts were pretty similar for candidates in group A and hinted toward a decline for candidates in diagnosis group B.
    - If the cohort were to reflect the 2015 LAS changes, it is possible that the results would show more of a difference in the same direction for candidates in diagnosis group B and less of a difference for candidates in diagnosis group D.
- One-year post-transplant mortality rates and counts by diagnosis
    - Within each diagnosis group the post-transplant mortality rates are similar across the DSA, 250 NM and 500 NM simulations.
    - The counts of deaths decreases for recipients in diagnosis group A with each broader distribution scenario, while the counts of deaths increase for recipients in group D with each broader distribution scenario. Nevertheless, the post-transplant mortality rates do not change much, even though the counts do, because there are more people transplanted in diagnosis group D in these simulations, which means there are more people at risk for post-transplant mortality.
- Transplant rates and counts by region
    - In the 250 NM simulation, transplant rates and counts were pretty similar compared to the DSA simulation in most regions, though it decreased in Region 2 and increased in Region 9.
    - In the 500 NM simulation, transplant rates increased even more in Region 9. The transplant rates were lower in Regions 8 and 11. This is a typical result with broader distribution – areas with higher transplant rates under current rules tend to see decreases in transplant rates when organs are distributed more broadly.
    - Transplant rates in Regions 1, 5, 6, 7 stayed pretty similar across the board.

- Waitlist mortality rates and counts by region
    - The waitlist mortality rates in the 250 NM simulations were similar in most regions when compared to the DSA simulation.
    - The waitlist mortality rates in the 500 NM simulations did not increase in any region, declined in Regions 2, 3, 4, 9 and 10, and remained similar in the remaining regions compared to DSA simulation.
    - The point estimates/death counts stayed the same or declined in all Regions.
- Post-transplant mortality by region is no different when comparing simulations.
- Waitlist mortality by distance
    - It is not possible to compute waitlist mortality by distance because distance as a metric does not exist until there is a donor-recipient pair, but waitlist mortality depends on what happens to candidates on the waitlist.
- Transplant counts by distance
    - In this context, "local" means transplants performed where the donor and the recipient are in the same DSA.
    - The number of local transplants progressively decreased in the 250 NM and 500 NM simulations. The majority of the transplants that were local under the DSA simulation were instead offered to and accepted by higher LAS candidates within the first 500 NM. This created a re-shuffling of where the transplants occur within those first 500 NM. In all simulations, the number of transplants that occur beyond 500 NM do not change.
    - The match run seeks the candidate with the highest LAS appropriate to the donor within the first unit of sharing.
        - For example, in the DSA-first simulation, only 424 transplants occurred in the distance between 150-<250 NM from the donor. But, in the 250 NM-first simulation, there were 1,299 transplants in the 150-<250 NM distance.
        - Similarly, in the 500 NM-first simulation, the largest number of transplants occurs in the distance between 250-<500 NM from the donor.
- Change in transplant counts by DSA
    - For the duration of the cohort, there were 40 DSAs with a lung transplant program. The size of each DSA is variable in number of candidates, recipients, and in physical distance.
    - There was not a lot of difference in the number of transplants for most DSAs across simulations. Declines were general observed in transplant programs located close to another transplant program but across a DSA border.
    - In those DSAs that demonstrated a decrease in transplants, the median LAS was lower as compared to those DSAs that demonstrated an increase in transplants, which was an expected outcome of broader distribution.
- Change in waitlist death counts by DSA
    - In almost every DSA the number of waitlist deaths declined; when that was not true, deaths increased by two or fewer.
    - The Committee questioned whether OPO performance contributed to these results: would a high-performing DSA that has only one transplant program experience fewer transplants post-change? The SRTR explained that, as informed by similar analyses for other organs, the answer is not that simple. There are multiple factors, including center listing behaviors, population density, as well as OPO performance, that contribute to difference in DSAs.
- Transplant rates and counts by LAS
    - In the 250 NM simulation, transplant rates declined for candidates with an LAS between 30-35 and increased for candidates with an LAS of 40 and above.

    - In the 500 NM simulation, transplant rates declined for candidates with an LAS less than 40 and increased for candidates with an LAS of 40 and above, dramatically so for candidates with an of LAS 50 and above.
        - This was an expected result informed by analysis performed in the new heart allocation system; when the sickest patients are given increased access to organs at a greater distance the transplant rates among those patients increases.
- Waitlist mortality rates and counts by LAS
    - In the 250 NM simulation, waitlist mortality rates were similar by LAS compared to the DSA simulation.
    - In the 500 NM simulation, waitlist morality rates are also pretty similar, but death counts declined for candidates with a LAS of 50 and above.
    - Counts decline for candidates in higher LAS groups, and so does time on the list.
- One-year post-transplant morality rates and counts by LAS
    - Within LAS groups post-transplant morality rates were similar across simulations, but were higher in higher LAS groups.
    - Counts also increased in high LAS groups but ranges overlapped across all simulations; more candidates were at risk for post-transplant deaths because more were being transplanted in those higher LAS groups.
- Transplant rates and counts by center volume
    - Center volume was defined as categories of transplant counts per center in a 2-year TSAM period. For a 2-year period, the TSAM added up how many transplants were performed at each center, then categorized the centers into the following groups by volume: <=20; 21-35; 36-75; 76-100; and >100.
    - Transplant rates declined in centers performing 36-75 transplants in the 250 NM simulation, and increased in centers performing more than 100 transplants in both the 250 NM and 500 NM simulations.
    - About 2/3 of recipients were transplanted in centers that perform either 36-75 transplants or greater than 100 transplants.
    - There was very little change in transplant rates among small volume centers (<=20 transplants) across all simulations.
- Waitlist mortality rates by center volume
    - In the 250 NM simulation waitlist mortality rates were similar, though point estimates declined in the 36-75 group and the 100+ group.
    - In the 500 NM simulation waitlist mortality rates declined decisively for the 36-75 group and the 100+ group.

The Lung Subcommittee will continue to discuss the results of this TSAM on its January 18, 2018 teleconference.