OPTN/UNOS Liver and Intestinal Organ Transplantation Committee
Meeting Minutes
June 21, 2018
Conference Call

Julie Heimbach, M.D., Chair
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Introduction

The Liver and Intestinal Organ Transplantation Committee met via teleconference on 6/21/2018 to discuss the following agenda item:

1. Discussion of Current Liver Allocation Policy

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Data summary:

Timeline was presented. Final comment to Executive Committee (EC) went out on Monday, June 18. Since Monday, EC has been reviewing comments and formulating a draft which will be sent to HRSA on June 22nd. EC has not made any final decisions at this point.

The Committee's recommendation was that the current policy needs continued modification, rather than the wholesale change, and some strategies for that were outlined. UNOS staff has outlined possible outcomes. There's a possibility the EC could recommend something different or ask the Committee to revise the proposal to one that does not include the region or the DSA, or HRSA could direct a specific change. The long-term prospects of DSA surviving judicial review are extraordinarily low. The Committee should start the process of formulating a replacement for DSA.

Summary of discussion:

A member pointed out eliminating DSA and having the 150-mile circle would mean region-wide sharing down to MELD of 15 plus the circle and the challenge of the marginal donors, DCD, and older donors. An expedited placement working group is working on that, but it's not done. Another option could be a circle for the local component. Having some consideration of closeness to donor for cost and logistics is helpful for the high-acuity patients.

The Chair agreed with the possibility of a small circle and a big circle. The Committee has two models currently. If they are asked to go the direction of eliminating the circle or region, they would have to go out to the community with another round of public comment with a new proposal. The Committee has worked on a model with districts or neighborhoods and could further develop that as well.

One Committee member felt DSA is not as defensible for multiple reasons. Regions are contiguous and bigger, and a regional-based distribution system could easily be modeled. He asked if the Committee needed to take DSAs out of allocation, and stick more to regional distribution. UNOS staff replied that HRSA asked UNOS the same question. In the long run, because the regions were not constructed with an allocation purpose, they have the same legal challenges that DSAs do. They would be more likely to succeed in an argument that says the unintended consequence of a region-based system is potentially greater in comparison to the benefit because the region-based system is more equivalent and has less variation than DSA.

Another Committee member agreed regions weren't designed for distribution. However, in circle plus region as area of distribution, it turns out the circle dominates the mathematical modeling

compared to the region when you add the circle, so it was suggested that perhaps it would be possible to use region plus circle.

One Committee member said the legal concern around DSA isn't that it's too small, the legal concern is that it's variable. If one wants to stay nearby because cold time matters or cost increases when shifting from ground to air, then there should be a system in place that reflects the infection point. However, it was pointed out that there is a relationship between the number of people in the DSA and the area of the DSA. Small DSAs by area, meaning not many miles, tend to have high population. In areas of smaller population, the DSAs formed to include larger land area. There are more logistical challenges with multiple centers and higher population in the first unit of distribution, which affects the efficiency of organ allocation. There was some debate over whether DSAs really accurately reflect population density since the population density within a specific DSA is more heterogeneous than homogenous.

The Chair asked the Committee what change in the model they wanted to move toward. A member felt that until the EC or HRSA tells the Committee to make changes, the answer would be speculative. The message from the Committee should be that a compromise was reached, changes were in play, and it would be an evolution. Committee members did not agree with using districts or neighborhoods for distribution during last policy change process. Maybe circles would be more palatable and have fewer unintended consequences, but it would also depend on those details. However, there has been disagreement among members of the liver transplant community on the definition of disparity and how it should be measured.

The discussions of EC have been that liver's situation is different from lung. There is already less dependence on geography. There is high chance of unintended consequences. A solution will take time, so the Secretary should allow time to work this out. Ultimately there are models that would better reflect cold time cost and the other issues in the final rule than the variation in DSAs. Potentially there could be a secretarial or judicial intervention at any point. The EC is looking at whether that will be changed in 6 months or 12 months, but is not looking to adopt a policy on its own or in a short amount of time. The Committee needs to use its regular process as much as possible in making changes, looking at models, and getting public feedback on those models.

Next Steps:

Final draft to the EC will be sent out to the Committee today.