

**OPTN/UNOS Minority Affairs Committee
Report to the Board of Directors
June 23-24, 2014
Richmond, VA**

**Meelie A. Debroy, MD, Chair
Jerry McCauley, MD Vice Chair**

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This report reflects the work of the OPTN/UNOS Minority Affairs Committee from 11/19/2013 through 3/18/2014.

Action Items

None

Committee Projects

1. MAC Educational Guidance on Patient Referral to Kidney Transplantation – Provider Resources

Public Comment: n/a

Board Approval: June 2013

The Committee has been studying inputs into the kidney allocation system to address barriers to transplantation for minority candidates. For the past few years, the Committee has studied delayed referral to transplant evaluation. Substantial published literature suggests that many patients suitable for kidney transplantation are never referred for transplant evaluation or referred late in the progression of their disease. This risk of delayed referral is greatest for minority patients. Late referral has negative medical consequences for patients and limits future opportunities for successful transplantation, as many patients who may have been suitable candidates initially wait too long on dialysis and then lose the ability to be considered for a transplant. Late referral also impacts preemptive transplantation and contributes to excess patient mortality.

A subcommittee of the MAC developed the *Educational Guidance on Patient Referral to Kidney Transplantation* to raise awareness among referring physicians, practitioners and their national societies about appropriate and timely patient referral to kidney transplantation. The guidance document was approved by the Board in June of 2013. The second phase of the project would convert the content in the guidance document into targeted education and instructional materials for providers. Products to be developed include a provider brochure, FAQ sheet, online articles, and other potential professional offerings. Completed products include incorporation of the referral message from the guidance document into a Kidney Allocation System (KAS) educational podcast and webinar, and inclusion in the KAS Toolkit. Other educational efforts, CME credits for example, would need to be pursued outside of the purview of the OPTN.

2. A Patient's Guide to Referral to Kidney Transplantation

Public Comment: n/a

Board Review: n/a

A joint subcommittee of the MAC and the Patient Affairs Committee (PAC), along with staff in the UNOS Communications Department, are collaborating to translate the content from the guidance document into a downloadable patient referral brochure. The brochure will serve as an educational resource for CKD and ESRD patients. The resource will highlight 3-5 high-level referral messages targeted to patients that will include:

- a definition of early referral and the benefits
- explanation of the referral process (to include pre-transplant processes that typically follow the referral)
- potential patient and provider barriers to referral
- presentation of the option of self-referral and how to initiate the process.

This work is occurring alongside the MAC project to develop educational/instructional programming on referral targeted to providers.

3. Kidney Referral Manuscript

Public Comment: n/a

Board Consideration: n/a

The *MAC Survey on Referral to Kidney Transplantation* was conducted to study the timing and rate of patient referral for kidney transplant evaluation. Survey results showed that although transplantation is the optimal treatment for ESRD, there is no established process in place for tracking referrals, or clear accountability for the referral process. Transplant centers generally do not have the authority or resources to determine if eligible patients are being referred for evaluation or even informed of transplant options. Providing current information to patients about eligibility and outcomes could help increase minority access to transplantation. Recommended approaches should incorporate patient-focused, provider- focused, and regulatory initiatives. The Committee has recently resumed work on this project following guidance from OPTN leadership on the presentation and internal review of the manuscript. The working group has almost completed the manuscript summarizing the survey results. The manuscript is expected to be completed by early summer, 2014.

4. MAC Comprehensive Review Article

Public Comment: n/a

Board Consideration: n/a

Numerous modifications to OPTN policies addressing inequities in access to kidney transplantation among ethnic groups, and significant increases in minority donation rates have not substantially improved the disparity in transplant rates of minority candidates as compared to whites. The work of the MAC has focused on comprehensive review and

study of the problem to identify policy-related as well as educational solutions that would advance minority access to transplantation.

For several years the Committee has been interested in developing a historical accounting of its work in the form of a review article. The focus and strategy of the manuscript has changed with the advent of new Committee leadership and Committee activities. In March, the Committee was informed that the working group has made significant progress in documenting MAC efforts that have impacted national kidney allocation policy. The article covers a 20-year span of OPTN policy development, citing examples of MAC initiatives that led to policy changes resulting in significant improvements in transplant outcomes for ethnic minority patients with end-stage renal disease. The draft manuscript is now 80% complete, with remaining work focused on the development of the dialysis waiting time pilot project timeline. The manuscript should be completed in late summer, 2014.

5. Dialysis Survey Manuscript

Public Comment: n/a

Board Consideration: n/a

The *MAC Dialysis Facility Survey* showed that minority dialysis patients had a perceived low level of knowledge and understanding of kidney transplantation, allocation policy, and participation in the public comment process. While survey results showed the majority of respondents had some understanding of transplant allocation policies, most reported no awareness of the public comment process, with only 2% ever having participated. Responses suggest an overall desire among dialysis patients to be involved in the public comment process. However, lack of knowledge about the process of policy development, limited access to the proposals, low rates of access and familiarity with the internet and e-mail may be hampering participation in public comment and patient input into transplant policy development.

MAC and UNOS staff have finalized the manuscript summarizing results of the MAC survey to conform to OPTN and HRSA requirements. The manuscript is awaiting HRSA approval prior to journal submission.

6. Educational Guidance on Informed Consent for Living Donors Representing Vulnerable Populations

Public Comment: N/A

Board Consideration: June 2015 (estimated)

Some potential living donors are at greater risk of developing ESRD post donation. These potential donors often represent traditionally underserved and/or vulnerable populations and may be more susceptible to coercion and other pressures to donate, despite the risk. They are younger in age at donation and/or are ethnic minorities who are less likely to receive adequate information about their future health risks. Despite the known underlying risk factors for specific donors, there is no uniformity within individual transplant programs in how potential living donors are counseled about their risks.

With the growth of the kidney transplant waiting list, living kidney donors (LKD) remain a significant source of donated organs. For several years, the Committee has been concerned about the safety of living donation for minority patients, particularly with respect to those individuals who donated their kidneys and may have developed ESRD post-donation. A manuscript published by the Committee in 2011 showed that although the overall incidence of ESRD in living kidney donors is very low, black and male living kidney donors were significantly more likely than white and female living kidney donors to develop ESRD following kidney donation. However, the increased risks did not appear to be significantly higher than those seen in the general population.

In July 2013, the Committee viewed an unpublished manuscript presentation from a recent American Transplant Congress (ATC) meeting which proposed to better understand the risk of ESRD attributable to live donation through a comparison of ESRD incidence in live donors to their healthy matched non-donor counterparts. While black/African American donors had the highest absolute risk of ESRD, the study found that they had the lowest relative risk increase in ESRD when compared with healthy non-donors. This supported the Committee's previous findings; however, it reinforced its concern regarding greater long term donation risks in black/African American donors compared with white/Caucasian donors. While the Committee remains supportive of expanding minority access to living donation, it is also interested in ensuring that vulnerable donors at high risk fully understand their risk factors when being counseled about being a potential donor.

The MAC is collaborating with several committees, including Living Donor, Transplant Administrators, Ethics, and Kidney, to develop the *Educational Guidance on Informed Consent for Living Donors Representing Vulnerable Populations* resource. The educational resource would target the professionals who initiate the informed consent discussion as part of the living donor evaluation, and would offer talking points a transplant professional could use to counsel patients representing vulnerable populations considering living donation who have known or potential risk factors. The resource is intended to help ensure that the practice of living donation among certain populations remains accessible and safe as a transplant option. Staff is conducting a literature search and developing an approach for defining vulnerable populations, prior to scheduling the initial conference call.

Committee Projects Pending Implementation

None

Implemented Committee Projects

None

Review of Public Comment Proposals

The Committee reviewed 8 of the 17 proposals released for public comment from March – June, 2014.

7. Kidney Paired Donation (KPD) Histocompatibility Testing Policies (Kidney Transplantation Committee)

The proposal presentation was followed by general discussion and comment by the Committee. Members discussed the time frame for retesting should a sensitizing event occur, and requested clarification of the terminology “unacceptable positive crossmatch occurring late in the chain.” The member was interested in whether this was the same as an “*unexpected*” positive crossmatch. It was responded by the committee representative that the term was changed in the proposal upon recommendation of the Histocompatibility Advisory Committee for monitoring purposes and redefined to include only those results which would impede transplantation. An unexpected positive crossmatch would not necessarily mean that the organ is unacceptable to the transplant program. The Committee also briefly discussed the continued variability in standards of histocompatibility labs across the country with regard to molecular typing.

Following the discussion, the committee determined that there was no inherent minority impact requiring formal comment or vote.

8. Proposal to Cap the HCC Exception Score at 34 (Liver and Intestinal Organ Transplantation Committee)

Following presentation of the proposal and brief discussion by the Committee, the Committee expressed its general support of the proposal. It was noted that this was an important first step in preventing HCC candidates with small treated tumors to surpass candidates with higher calculated MELD scores for transplantation. It was also noted that there is another liver proposal planned to be distributed in the near future to limit the entry of patients with extremely stable well treated single lesion tumors to advance on the list.

The committee did not identify an inherent minority impact that would require comment or vote.

9. Proposal to Delay HCC Exception Score Assignment (Liver and Intestinal Organ Transplantation Committee)

The proposal presentation was followed by brief discussion by the Committee. It was noted that candidates with HCC exceptions receive relatively high priority, which overestimates their risk of mortality on the waiting list. It was suggested that there is a minority/socioeconomic impact in that HCC patients with sufficient resources are able to travel to a region with a lower median MELD at transplant, list with a second transplant program, and possibly receive a transplant more quickly. It was noted that the redistricting work being conducted by the Liver Committee will better address these instances; however, the proposal will help equalize the situation for patients without resources to list at more than one transplant program.

It was also suggested that the proposal may also help improve access for minority liver transplant candidates, who in general have decreased access to liver transplantation and present much later in the course of their liver disease with larger and non-transplantable tumors.

The Committee noted its broad support of the proposal for the reasons mentioned above but declined a formal vote.

10. Proposal for Adolescent Classification Exception for Pediatric Lung Candidates (Thoracic Organ Transplantation Committee)

The MAC reviewed this proposal in concert with the results of data previously requested by the Ethics Committee to identify if there are issues preventing access to these organs in lung transplant programs. The Ethics Committee was interested in examining data to determine if there are high turn down rates for these organs, and if so, what the ethical considerations of such practices would be as they relate to access and public transparency. A member of the Committee inquired whether there was any intent to build the pediatric lung exception into the existing pediatric allocation policy with some considerations incorporated for body size, etc. rather than require an exception that would need to be requested. It was responded that this was considered and discussed by the committee but not ultimately recommended.

Although the data did not reveal any glaring discrepancies in the current system, the Committee noted its general support of the proposal. The Committee opined that the proposal promotes the opportunity to continue increased access to organs by providing an opportunity for uniquely situated pediatric candidates to gain increased priority for an older and larger donor pool, thereby reducing the rate of waiting list mortality for pediatric candidates.

The Committee did not identify an inherent minority impact necessitating a formal vote.

11. Expanding Candidate and Deceased Donor HLA Typing Requirements to Provide Greater Consistency Across Organ Types (Histocompatibility Committee)

The proposal presentation was followed by brief discussion by the committee. In response to the specific feedback requested by the Histocompatibility Committee, the committee made reference to its support of the previous Histocompatibility proposal disapproved by the Board, and noted that it continues to strongly affirm the addition of unacceptable antigen fields for DQA and DPB loci with support for UNOS programming to be added to the system to automatically avoid those donors when unacceptable antigens are listed. Members noted that with increased national sharing, if these loci are not added to the system, it may result in unexpected positive crossmatches for organs accepted for hard to match intended recipients which may have traveled some distance for transplantation. The Committee also noted that this information would be essential in the ability to perform a virtual crossmatch.

The Committee did not identify an inherent minority impact that would require a vote.

12. Proposal to Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors (Living Donor Committee)

The Committee briefly discussed the rationale behind removal of all of the references to the term “potential living donor” and replaced with the term “living donor.” It was explained by committee staff that this term has never been officially defined in policy and may be interpreted differently by individual transplant programs. As such, it may be difficult to determine which requirements would apply to a potential living donor versus an actual living donor, if an individual could be at different stages in the process depending on the transplant program.

Following presentation of the proposal and the brief discussion, the Committee did not identify an inherent minority impact that would require formal comment or vote.

13. Proposal to Modify Existing or Establish New Requirements for the Psychosocial and Medical Evaluation of all Living Donors (Living Donor Committee)

Following presentation of the proposal and brief discussion by the committee, the MAC did not identify an inherent minority impact that would require formal comment or vote.

14. Proposal to Notify Patients Having an Extended Inactive Status (Transplant Coordinators Committee)

Following the presentation, the committee discussed the proposal at some length. Although the committee supported the overall goal of the proposal to increase patient awareness of their inactive waiting list status, members strongly suggested that the proposal would only help a small focused cohort of the waiting list based on the many reasons patients are placed in inactive status. The committee also expressed concern that the proposal would not achieve the desired result and would only serve to generate more work for the transplant program. This could be especially problematic if candidates who are inactive due to medical issues that still need to be addressed or treated (cancer, doctor recommended weight loss regimen, thoracic candidates on an LVAD, etc.) are receiving regular reminders about their known inactive status. It was suggested that the patients who might benefit from an annual waiting list status update would be those with reversible statuses.

The committee briefly considered an amendment to the proposal recommending that the notifications be sent in an annual mass mailing to specifically identified inactive candidates instead of a mailing sent to all inactive candidates on the anniversary of their inactive date. However, in final deliberations, the committee determined that the proposal was unnecessary because many of the issues outlined in the proposal would eventually be resolved. This would be especially true with kidney candidates due to the implementation of the new KAS and the incorporation of dialysis waiting time into the algorithm, which is driving transplant programs to address inactive candidates as part of the data clean up.

The Committee voted to disapprove the proposal by a vote of 17 for, 4 against, and 0 abstentions.

Other Committee Work

15. DR/DQB Mismatch Research (Histocompatibility Committee)

The Committee has been interested in the work of the Histocompatibility Committee in exploring whether additional priority should be awarded DQB matching in kidney allocation. During discussion of this project, the Committee has cautioned against overemphasizing any single element in the allocation system and potentially disadvantaging minority candidates, without clear evidence that the change would result in significant improvement graft survival for all candidates. The Committee is contributing to this project. For more information on this project, see the **Histocompatibility Committee's Report to the Board.**

16. Variance to KAS/CPRA Points for Patients Undergoing Desensitization (Histocompatibility Committee)

The Histocompatibility Committee is currently working on a policy change or a variance to allow sensitized patients undergoing sensitization to maintain priority associated with CPRA for the period of time when the unacceptable antigens are removed. The Committee is contributing to this project. For more information on this project, see the **Histocompatibility Committee's Report to the Board**.

17. KPD Participation Survey (KPD Work Group)

The Committee was provided with highlights of the KPD Participation survey developed by the KPD Working Group to assess barriers to KPD program participation. The MAC has been discussing KPD program participation over the last several meetings and the committee expressed interest in examining minority access to KPD and barriers to programmatic access for participation in KPD, particularly in geographic areas with a large ethnic composition on the waiting list. As the KPD survey results were developed to assess center barriers rather than individual candidate barriers, the data did not reveal much to address the specific question of the Committee. It was noted that the living donor transplant rate for African Americans since the start of the OPTN KPD Pilot Program is 50% higher than the national rate, though the program is not getting all of the candidates it could. Members were encouraged to advocate within their regions for more participation to help improve the perception and buy in of the program, as well as its success rate. The MAC is continuing to contribute to KPD programmatic and policy projects. For more information on this project, see the **Kidney Committee's Report to the Board**.

18. Kidney Allocation System (KAS) Implementation (Kidney Committee)

The MAC was provided with highlights of current and upcoming KAS implementation timelines as well as upcoming educational opportunities. The Committee is contributing to this project. For more information on this project, see the **Kidney Committee's Report to the Board**.

19. Geographic Distribution: Update on Kidney Allocation Equity Measures (Kidney Committee)

The Kidney Committee is attempting to define geographic disparity metrics for the kidney allocation system as charged by the Board. The MAC is very interested in this issue and has opined that minority patients experience disadvantage in terms of lack of information on transplant as an option, but also have the additional burden of reduced access due to geographic location. The MAC is contributing to this project. For more information on this project, see the **Kidney Committee's Report to the Board**.

20. Simultaneous Liver-Kidney (SLK) Allocation Review (Kidney Committee)

The Kidney Committee is in the early stages of considering whether to develop a policy proposal to address simultaneous liver-kidney allocation. The Committee has been following this issue for a number of years due to a concern that SLK transplantation may be reducing access to transplantation for minority kidney candidates. When allocated as

part of a SLK transplant, kidneys may be transplanted into candidates who would have regained their native renal function following a solitary liver transplant, further disadvantaging minority candidates awaiting transplantation who are already overrepresented on the kidney waiting list.

The Committee viewed SLK data during its July 2013 meeting in an attempt to determine if SLK transplants are drawing organs away from kidney alone candidates. The committee discussed potential minority impacts including the ethnic distribution of SLK transplantation and whether there are significant differences between the demographics of waiting list candidates versus the demographics of those candidates receiving SLK transplants, variance in SLK listing criteria and selective practice patterns, and false positives as an area of concern, since many minorities are unable to bring a living donor organ into the pool. Although the Committee was unable to directly identify a specific minority issue from the data presented; members expressed interest in following the data as it is presented to the POC, and requested continued collaboration with the organ specific committees with regard to potential policy changes. The MAC is contributing to this project. For more information on this project, see the **Kidney Committee's Report to the Board**.

21. MAC Abstract Submission on Ethnic Disparity in the OPTN Kidney Paired Donation Pilot Program (KPDPP) Participation

The Committee was updated on an abstract submitted to the World Transplant Congress (WTC) meeting entitled, "Ethnic Disparity in the OPTN Kidney Paired Donation Pilot Program Participation." The abstract resulted from the regular ongoing data request from the Committee to compare the ethnic composition of KPDPP intended candidates with all wait listed candidates at KPDPP transplant programs. Although blacks were transplanted at a higher rate than their representation in the KPDPP population, minority participation in KPDPP is less than expected based on the demographics of the KPD pilot program center waiting list. The abstract has not yet been accepted but the committee will be updated on its status.

22. Review and Discussion of the Pediatric Lung Exception Interim Policy (Thoracic Committee)

The Committee has expressed interest in examining if there was equivalent access for ethnic minority candidates under the interim pediatric lung exception policy implemented in June 2013 and slated to expire in June 2014. The temporary policy was developed following a claim that the lung allocation policy unfairly restricted access to patients less than 12 years old. The Committee viewed Lung Review Board (LRB) requests for adolescent data and data originally requested by the Ethics Committee in June 2013 (**Exhibit A**) to identify whether there were any minority impacts. Due to the small number of patients who have received exceptions under the interim policy, minority access to these organs is unable to be determined. For more information on this project, see the **Thoracic Committee's Report to the Board**.

23. Modification of Heart Allocation System (Thoracic Committee)

The committee was informed that the Heart Subcommittee of the Thoracic Committee continues to work on developing a proposal to modify the current heart allocation system. The Committee is interested in review of all major organ allocation policy

development efforts for minority impacts. The Committee is contributing to this project. For more information on this project, see the **Thoracic Committee's Report to the Board**.

24. Liver Distribution Redesign Modeling (Liver Committee)

The Committee reviewed updated proposed liver redistricting maps resulting from the Liver Committee work to develop a more geographically equitable liver allocation/distribution area (**Exhibit B**). The Committee requested an examination of the impact of redistricting on candidates by ethnicity in general, and pediatrics. The data presented by the SRTR showed no significant differences between alternatives for percent of transplants to female ($p=.60$) with significantly larger numbers of pediatric transplants ($p < .001$) resulting from the increased sharing. There was no significant change in percent of transplants to black candidates ($p=.28$); however, the data showed a statistically significant increase in the percent of transplants to Hispanic candidates ($p=0.02$) and a decrease in percent of transplants to white candidates ($p<0.001$). The MAC is contributing to this project. For more information on this project, see the **Liver Committee's Report to the Board**.

25. MAC A2/A2B Variance Manuscript

The Committee was updated on completion of the manuscript on the development and results of the Minority Affairs Committee sponsored variance to transplant A2 and A2B donor kidneys into B recipients. The manuscript presents the scientific and historical perspective of the A2/A2B protocol, which is being incorporated into the new KAS.

Meeting Summaries

The committee held meetings on the following dates:

- November 19, 2013
- March 18, 2014

Meeting summaries for this Committee are available on the OPTN website at:

<http://optn.transplant.hrsa.gov/members/committeesDetail.asp?ID=19>.

OPTN Ethics Committee
Request

Descriptive Data

Offer Acceptance Rates for 0-11 Lung Candidates by Region and Donor Age

Prepared for:

OPTN Ethics Committee Meeting
October 21, 2013

By:

Leah Edwards, Wida Cherikh, and Tim Baker
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BACKGROUND/PURPOSE

In June 2013 the Ethics Committee was asked to provide guidance to the OPTN/UNOS Executive Committee on the ethical issues to consider when reviewing allocation policies. This request came as a result of the media attention on the plight of a 10-year-old pediatric lung candidate whose parents successfully petitioned to get her registered on the adult lung waiting list after a lawsuit claiming that the current lung allocation system was unfair and capricious.

The Murnaghan case focused on a claim that allocation policy unfairly restricted access but the Ethics Committee is concerned that access may also be significantly impacted by center turn-down practices, which may vary significantly. The Committee would like to look at the data to see if in fact there are high turn down rates and if so discuss what the ethical considerations of such practices might be as related to access and public transparency. The Committee intends to consider this with the Pediatric Transplantation Committee and the Thoracic Transplantation Committee in order to better understand clinical context for high turn down rates and to work with those Committees on how best to address any ethical issues raised by the data review.

WORK PLAN ITEM ADDRESSED

Increasing access to transplant and the Secretary's request to review lung allocation policy.

COMMITTEE REQUEST

For lung candidates 0-11 years old, tabulate within each region:

- the number of centers
- the number of candidates
- the number of centers receiving at least one lung offer by donor age
- the number of donors from whom a lung offer was made by donor age
- the number of donors from whom a lung offer was accepted by donor age
- the percentage of donors from whom a lung offer was accepted by donor age

DATA AND METHODS

Data Sources:

Information provided in this report is based on OPTN data as of August 23, 2013, and is subject to change based on future data submission or correction.

Cohort and Methods:

The current analysis included information about candidates waiting for lung alone transplant. Candidates waiting for any other organ including those waiting for heart-lung were excluded.

Candidates aged 0-11 ever active on the lung alone waiting list and offers made between 1/1/12 and 5/31/13 were included in the analysis. Age for candidates ever waiting was determined based on the maximum of age at listing or age at start of period, whereas age at time of offer was used to count offers.

The number of centers with at least one active candidate aged 0-11 and the number of candidates aged 0-11 ever waiting were tabulated by region. Lung offers were tabulated for candidates who

were 0-11 years old at time of offer, stratified by region and donor age (0-5 years, 6-11 years, 12-17 years, and 18+ years). The offer tabulations were limited to donors in which at least one lung was accepted for transplant. A center may have multiple offers from one match. If both lungs were refused for the first two candidates on the match run and then accepted for the third candidate, this would be counted as 3 offers and 1 offer accepted in the tabulation.

All regions with only one lung program are reported in a combined grouping.

RESULTS

Table 1 shows the number of candidates aged 0-11 ever actively waiting on the lung alone list, the number of centers with candidates aged 0-11, and lung offers made to candidates aged 0-11 during 1/1/12-5/31/13, stratified by region and donor age. Since Region 2 was the only region with more than one transplant program during the analysis period, all other regions with only one lung program were reported in a combined grouping. Due to small numbers of candidates and offers, the results should be interpreted with caution.

- *Candidates:* Between 1/1/12 and 5/31/13, there were 10 candidates aged 0-11 ever actively waiting for a lung alone transplant at two transplant centers in Region 2 and 38 candidates aged 0-11 at five centers in all other regions.
- *Offers:*
 - Among the 10 candidates aged 0-11 in Region 2, 2 (20%) had at least one offer from 0-5 donors, 6 (60%) had at least one offer from 6-11 donors, 4 (40%) had at least one offer from 12-17 donors, and 2 (20%) had at least one offer from adult donors.
 - Among the 38 candidates aged 0-11 in all other regions, 16 (42%) had at least one offer from 0-5 donors, 11 (29%) had at least one offer from 6-11 donors, none received any offer from 12-17 donors, and 2 (5%) had at least one offer from adult donors.
- *Offer/acceptance rate:*
 - In Region 2, the offer acceptance rate among candidates aged 0-11 was 50% from 0-5 donors and 0% from donors of any other age group.
 - In all other regions, the offer acceptance rate among candidates aged 0-11 was 93% from 0-5 donors, 56% from 6-11 donors, and 50% from adult donors.

Table 1. Number of lung alone candidates aged 0-11 ever active on the waiting list, number of centers with lung candidates aged 0-11, and lung offers/acceptances for candidates aged 0-11 for matches run during 1/1/12-5/31/13 by region and donor age

* All donors in this analysis had at least one lung accepted for transplant, but not all of the acceptances

Region	# of centers with candidates aged 0 – 11	# of candidates ever actively waiting	Donor age	Offer/acceptance information					
				# of centers receiving at least 1 offer	# of candidates with at least 1 offer	% of candidates with at least 1 offer	# of donors with at least 1 offer	# of donors with an acceptance	% of donors with an acceptance*
2	2	10	0 - 5	1	2	20.0	2	1	50.0
			6 - 11	2	6	60.0	7	0	0
			12 - 17	1	4	40.0	4	0	0
			18+	1	2	20.0	2	0	0
			All	2	8	80.0	15	1	6.7
All Other	5	38	0 - 5	3	16	42.1	15	14	93.3
			6 - 11	5	11	28.9	9	5	55.6
			18+	2	2	5.3	2	1	50.0
			All	5	27	71.1	26	20	76.9
			U.S.	7	48	0 - 5	4	18	37.5
6 - 11	7	17				35.4	11	5	45.5
12 - 17	1	4				8.3	4	0	0
18+	3	4				8.3	4	1	25.0
All	7	35				72.9	35	21	60.0

were for candidates 0-11 years old. Therefore, although the donor acceptance rate was 100%, it was only 60% for the candidates aged 0-11 as shown in this table.

SUMMARY

- There were 48 lung alone candidates aged 0-11 years ever active on the waiting list during the time period of this analysis (1/1/12-5/31/13).
- There were 7 lung transplant programs with at least one candidate aged 0-11 years ever actively waiting during the time period of this analysis
- Almost 73% of the 0-11 year old candidates received at least 1 organ offer during this time period, and the rate was similar for candidates in Region 2 (80%) and for candidates in other regions (71%).
- Among candidates aged 0-11 ever active on the lung list and who received an offer between 1/1/12 and 5/31/13,
 - Acceptance rate was highest from 0-5 donors (94%); this age group also had the highest acceptance rate of all donor age groups in Region 2 (50%) and all other regions (93%).
 - Acceptance rates were lower in Region 2 as compared to all other regions within each of the donor age groups.

APPENDIX 1

Lung Allocation Ordering

(For complete details of the lung allocation see Policy 3.7).

Donors 18 years and older	Donors 12-17 years	Donors 0-11 years
Local candidates 12 years and older, ABO-identical. Sorted by descending LAS	Local candidates 12 -17 years, ABO-identical. Sorted by descending LAS	Local + Zone A + Zone B Priority 1 candidates, 0-11 years, ABO-identical.
Local candidates 12 years and older, ABO-compatible. Sorted by descending LAS	Local candidates 12-17 years, ABO-compatible. Sorted by descending LAS	Local + Zone A + Zone B Priority 1 candidates, 0-11 years, ABO-compatible
Local Priority 1 candidates, 0-11 years, ABO-identical	Local Priority 1 candidates, 0-11 years, ABO-identical	Local + Zone A + Zone B Priority 2 candidates, 0-11 years, ABO-identical.
Local Priority 1 candidates, 0-11 years, ABO-compatible	Local Priority 1 candidates, 0-11 years, ABO-compatible	Local + Zone A + Zone B Priority 2 candidates, 0-11 years, ABO-compatible
Local Priority 2 candidates, 0-11 years, ABO-identical	Local Priority 2 candidates, 0-11 years, ABO-identical	Local + Zone A candidates 12 -17 years, ABO-identical. Sorted by descending LAS
Local Priority 2 candidates, 0-11 years, ABO-compatible	Local Priority 2 candidates, 0-11 years, ABO-compatible	Local + Zone A candidates 12-17 years, ABO-compatible. Sorted by descending LAS
Zone A candidates 12 years and older, ABO-identical. Sorted by descending LAS	Local candidates 18 years and older, ABO-identical. Sorted by descending LAS	Local candidates 18 years and older, ABO-identical. Sorted by descending LAS
Zone A candidates 12 years and older, ABO-compatible. Sorted by descending LAS	Local candidates 18 years and older, ABO-compatible. Sorted by descending LAS	Local candidates 18 years and older, ABO-compatible. Sorted by descending LAS
...

Notes:

- Local = donor hospital and candidate's listing center are within the same donation service area (DSA)
- Zone A = donor hospital and candidate's listing center within 500 miles but outside of DSA
- Zone B = donor hospital and candidate's listing center between 500 and 1000 miles, but outside of DSA

Offer Acceptance Rates for 0-11 Lung Candidates by Region and Donor Age

OPTN Ethics Committee
October 21, 2013

OPTN



Background

In June 2013 the Ethics Committee was asked to provide guidance to the OPTN/UNOS Executive Committee on the ethical issues to consider when reviewing allocation policies.

- This request came as a result of the media attention on the plight of a 10-year-old pediatric lung candidate whose parents successfully petitioned to get her registered on the adult lung waiting list after a lawsuit claiming that the current lung allocation system was unfair and capricious.
- The Murnaghan case focused on a claim that allocation policy unfairly restricted access but the Ethics Committee is concerned that access may also be significantly impacted by center turn-down practices, which may vary significantly.

The Committee would like to look at the data to see if in fact there are high turn down rates and if so discuss what the ethical considerations of such practices might be as related to access and public transparency.

- The Committee intends to consider this with the Pediatric and Thoracic Transplantation Committees to better understand clinical context for high turn down rates and to work with those Committees on how best to address any ethical issues raised by the data review.

OPTN



Request

For lung candidates 0-11 years old, tabulate within each region:

- the number of centers
- the number of candidates
- the number of centers receiving at least one lung offer by donor age
- the number of donors from whom a lung offer was made by donor age
- the number of donors from whom a lung offer was accepted by donor age
- the percentage of donors from whom a lung offer was accepted by donor age

OPTN



Data and methods

Data: OPTN data as of August 23, 2013. Data subject to change based on future data submission or correction.

Cohorts and methods:

Candidates waiting for lung alone transplant; candidates waiting for other organs (including heart-lung) were excluded. Candidates aged 0-11 ever active on the lung alone waiting list and offers made between 1/1/12 and 5/31/13

Centers with at least one active candidate aged 0-11

Lung offers for candidates who were 0-11 years old at time of offer, for donors in whom at least one lung was accepted for transplant.

A center may have multiple offers from one match. If both lungs were refused for the first two candidates on the match run and then accepted for the third candidate, this would be counted as 3 offers and 1 offer accepted in the tabulation.

All regions with only one lung program are reported in a combined grouping

OPTN



Lung candidates, centers, and offers: 1/1/12-5/31/13

Region	# of centers with candidates aged 0 – 11	# of candidates ever actively waiting	Offer/acceptance information				
			Donor age	# of centers receiving at least 1 offer	% (N) of candidates with at least 1 offer	# of donors with at least 1 offer	% (N) of donors with an acceptance*
2	2	10	0 - 5	1	20.0% (2)	2	50.0% (1)
			6 - 11	2	60.0% (6)	7	0% (0)
			12 - 17	1	40.0% (4)	4	0% (0)
			18+	1	20.0% (2)	2	0% (0)
			All	2	80.0% (8)	15	6.7% (1)
All other regions	5	38	0 - 5	3	42.1% (16)	15	93.3% (14)
			6 - 11	5	28.9% (11)	9	55.6% (5)
			12-17	0	-	0	-
			18+	2	5.3% (2)	2	50.0% (1)
			All	5	71.1% (27)	26	76.9% (20)

* All donors in this analysis had at least one lung accepted for transplant, but not all of the acceptances were for candidates 0-11 years old.



Results for lung candidates 0-11 years old

- **Candidates:** There were 48 lung alone candidates aged 0-11 years ever active on the waiting list between 1/1/12 and 5/31/13
- **Centers:** There were 7 lung transplant programs with at least one candidate aged 0-11 years ever actively waiting
- **Offer rate:** The percentage of 0-11 year old candidates who received at least 1 organ offer was similar for candidates in Region 2 (80%) and for candidates in other regions (71%).
- **Offer acceptance rates:**
 - By donor age group, the rate was highest for 0-5 year old donors (50% in Region 2, and 93% for all other regions combined).
 - Rates were lower in Region 2 compared to other regions for all donor age groups combined (7% vs. 77%) and within each of the donor age groups.



Due to small numbers of candidates and offers, the results should be interpreted with caution.



OPTN/UNOS Thoracic and Pediatric Committees

Lung Allocation Policy Review
June 6, 2013

OPTN



Background data, 9/12/10-3/11/13

Age	No. of Active REGs on Lung WL	No. of REGs also on Heart-Lung WL	No. of Deceased Donor Lung Transplants	No. of Deceased Donors Recovered for Transplant	No. of Deceased Lung Donors Recovered for Transplant
0 - 5	54	12	24	846	32
6-11	49	7	16	341	43
12-17	115	10	57	937	358
18+	7,323	93	4,395	18,059	3,919

Notes:

- For registration numbers, age was determined based on maximum of age at listing or age at start of period; for transplant numbers, age at transplant was used.
- Number of transplants Included lung transplants with other organ(s), except heart-lung.

OPTN



Number of lung registrations with offers or acceptance by age, 9/12/10-3/11/13

	REGs Ever Active	REGs with at Least 1 Offer		REGs with 3+ Offers or Acceptance		REGs with an Acceptance	
	N	N	%	N	%	N	%
Age							
0 - 5	54	29	53.7	27	50.0	26	48.1
6-11	49	34	69.4	29	59.2	18	36.7
12-17	115	100	87.0	88	76.5	62	53.9
18+	7,323	6,826	93.2	6,262	85.5	4,396	60.0

Notes:

- Included lung registrations with or without any other organ(s).
- Age was determined based on maximum of age at listing or age at start of period.



Number of lung registrations with offers or acceptance by age, 9/12/10-3/11/13

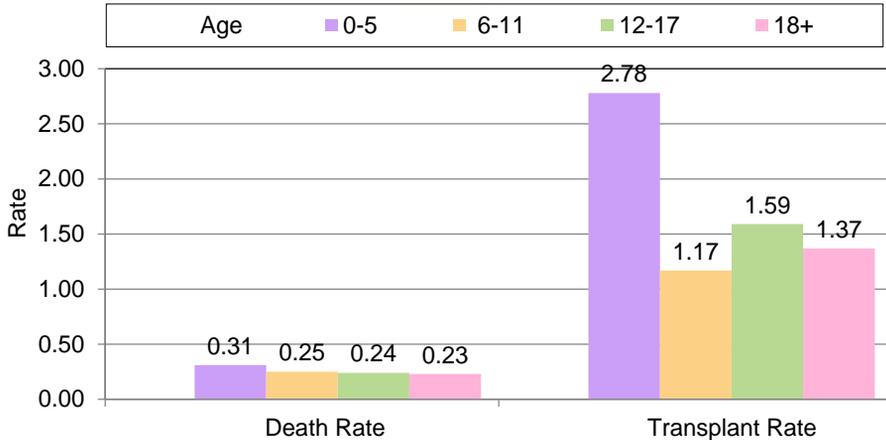
		REGs Ever Active	REGs with at Least 1 Offer		REGs with 3+ Offers or Acceptances		REGs with an Acceptance	
		N	N	%	N	%	N	%
Region	Age							
2	0-5	11	4	36.4	3	27.3	2	18.2
	6-11	14	10	71.4	8	57.1	1	7.1
	12-17	25	20	80.0	18	72.0	9	36.0
	18+	1,067	989	92.7	895	83.9	650	60.9
All others combined	0-5	43	25	58.1	24	55.8	24	55.8
	6-11	35	24	68.6	21	60.0	17	48.6
	12-17	90	80	88.9	70	77.8	53	58.9
	18+	6,256	5,837	93.3	5,367	85.8	3,746	59.9

Notes:

- Included lung registrations with or without any other organ(s)
- Age was determined based on maximum of age at listing or age at start of period



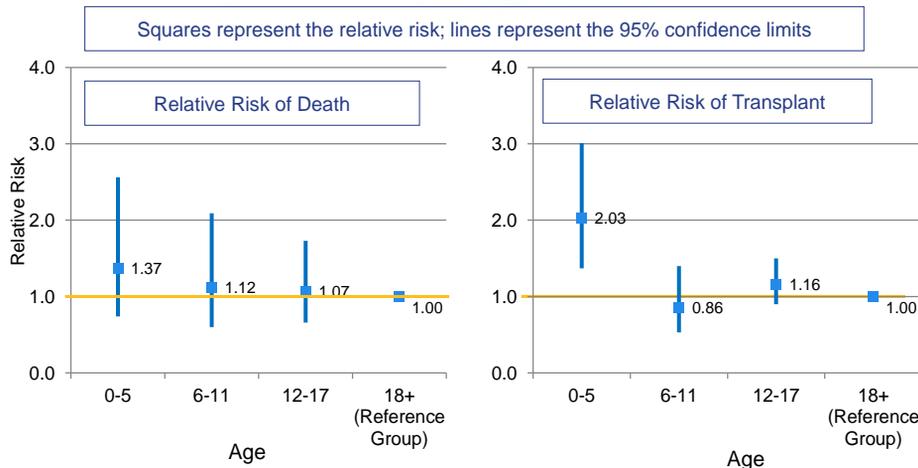
Death and transplant rates and per patient year by age for lung alone candidates ever waiting during 9/12/10-3/11/13



Notes: Age was determined based on the maximum of age at listing or age at start of period; Deaths included removals for too sick; Transplant rate was calculated per active patient year.



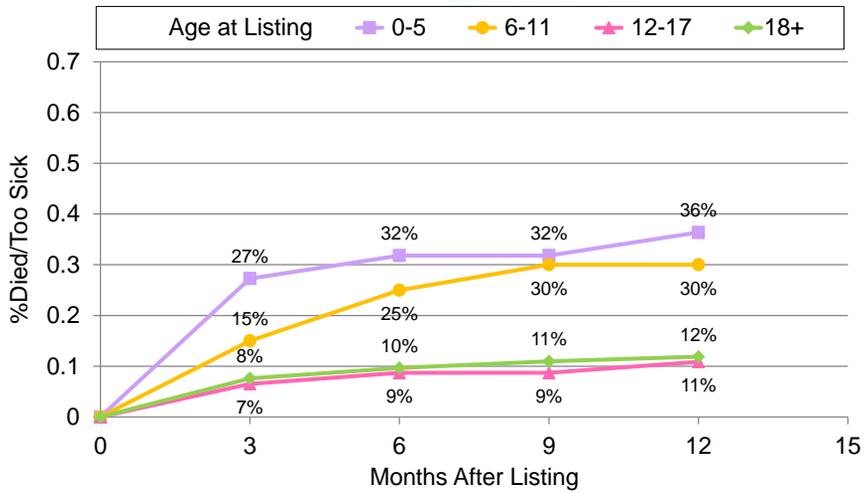
Unadjusted relative risk of death and transplant by age group for lung alone candidates ever waiting during 9/12/10-3/11/03



Note: Age was determined based on maximum of age at listing or age at start of period; Deaths included removals for too sick.



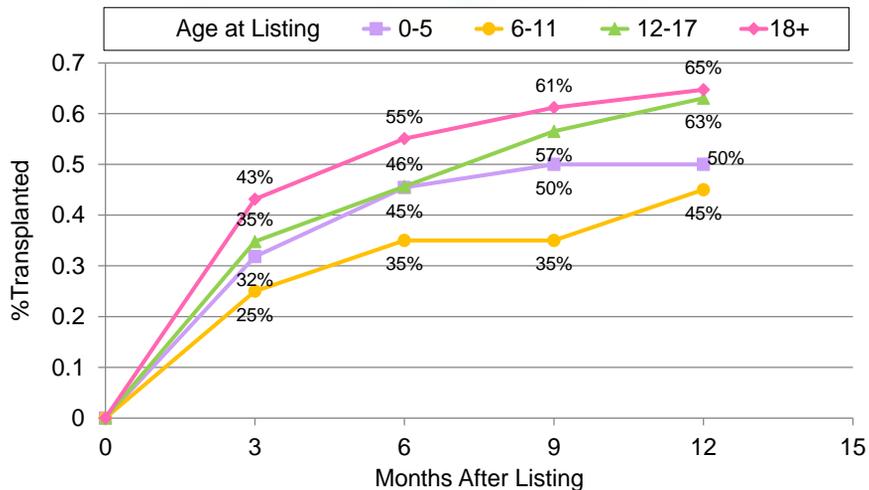
Cumulative probability of death by age for lung alone additions during 9/12/10-3/11/12



Note: Deaths included removals for too sick.



Cumulative probability of transplant by age for lung alone additions during 9/12/10-3/11/12



Liver Redistricting's Impact

Sommer Gentry, PhD
Dept Mathematics
US Naval Academy

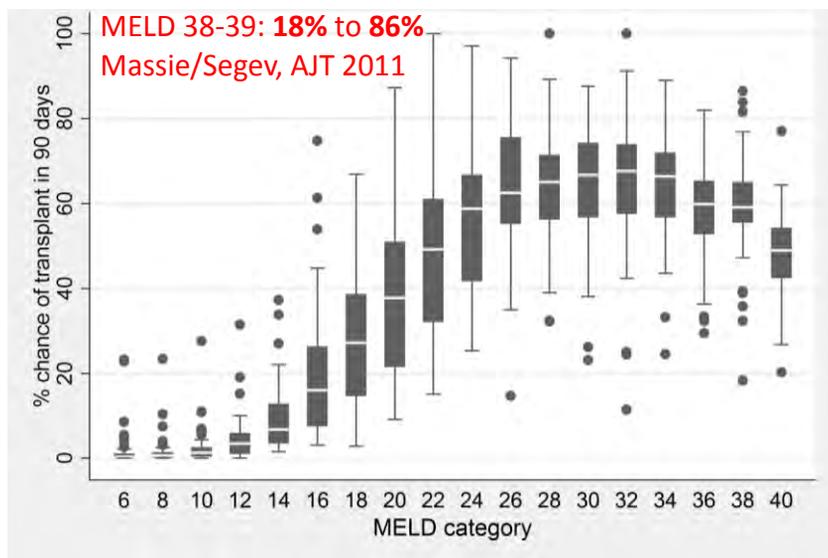
Eric Chow, MS
Dept Surgery
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Dorry Segev, MD, PhD
Surgery, Epidemiology, and Biostatistics
Johns Hopkins University

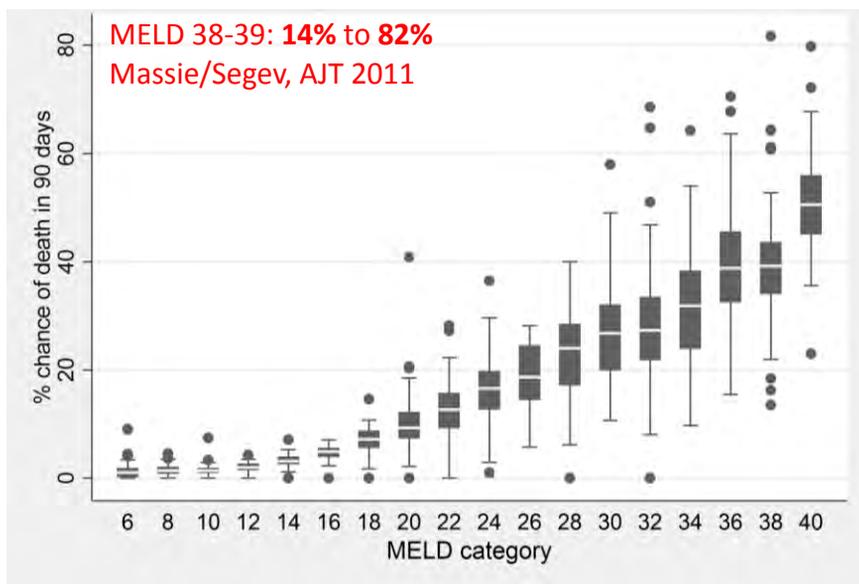
On behalf of the Scientific Registry of Transplant Recipients

**FINAL RULE: "NEITHER PLACE OF
RESIDENCE NOR PLACE OF LISTING
SHALL BE A MAJOR DETERMINANT OF
ACCESS TO A TRANSPLANT."**

Motivation: Transplant Rates, by OPO



Motivation: Death Rates, by OPO



Overview: optimized redistricting

- Minimize *total disparity*
 - Disparity = difference between number of donors a region *should* have (if organs went to highest MELD patient anywhere in the country) and number of donors in a proposed district
 - Minimize sum of these disparities over all districts
- Subject to constraints
(least geographic disparity achievable through the allocation system is under national share)

AJT, October 2013

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Addressing Geographic Disparities in Liver Transplantation Through Redistricting

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N. Dzebashvili⁵, P. R. Salvalaggio⁶,
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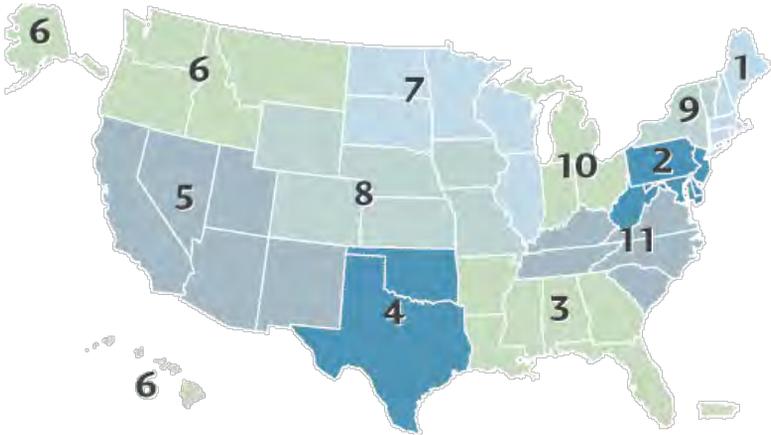
OPTN Liver committee choices

- The number of districts should be at least 4 and no more than 8.
- Minimum number of transplant centers per district is 6.
- The maximum median travel time between DSAs placed in the same district is 3 hours.
- The number of waitlist deaths under redistricting must not be statistically significantly higher than in the current system.

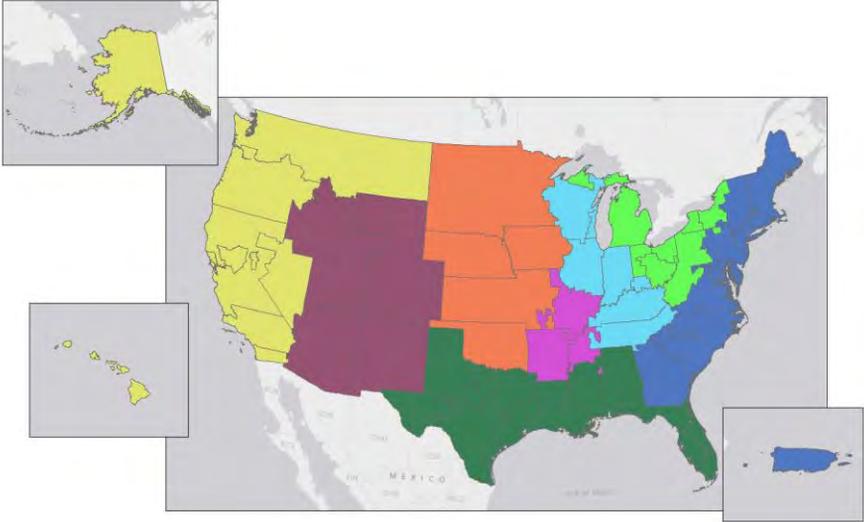
MAC questions

- Examine potential impact of redistricting on candidates by ethnicity, gender, pediatric status

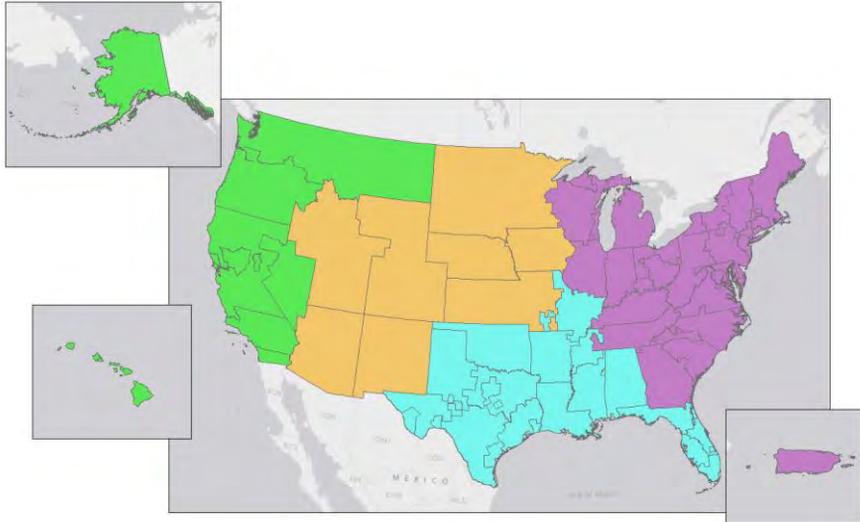
OPTN Regions



8 districts



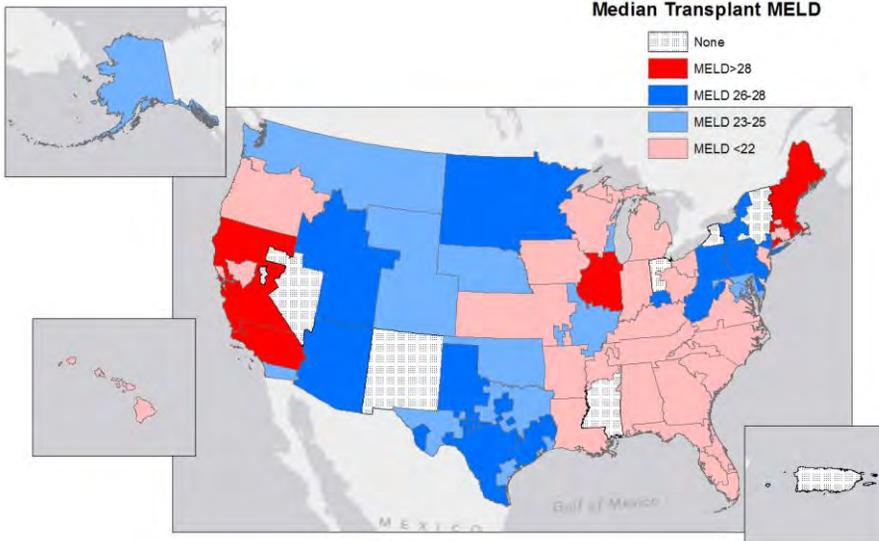
4 districts



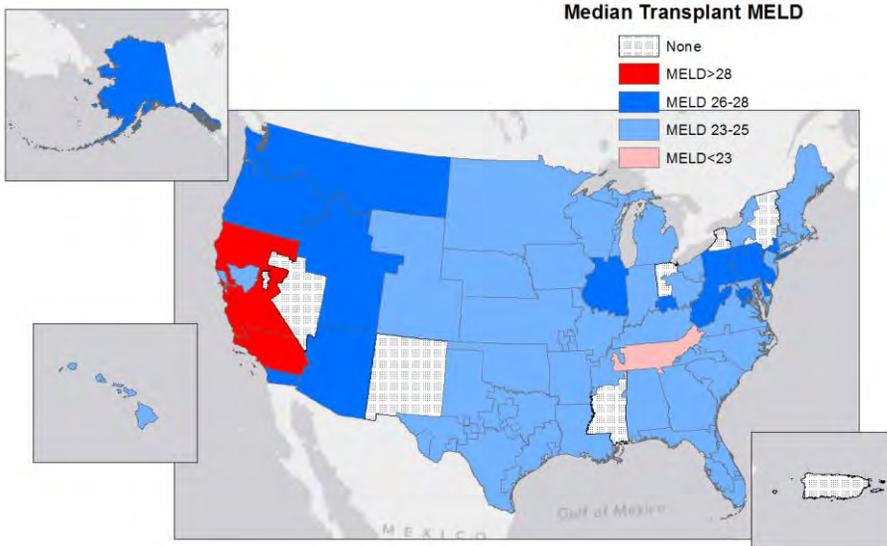
Optimize Redistricting Plan

Districts	<i>Standard deviation of tx MELD</i>	% MELD <15	% MELD >25	% Pediatric	Net total deaths	<i>Net waitlist deaths</i>
4	1.87	2.5%	64.3%	8.7%	-553.8	-581.1
8	2.08	3.7%	59.6%	8.1%	-332.4	-342.1
LocalFirst	3.01	5.8%	50.1%	7.5%	0	0
Regional	3.26	5.5%	54.3%	7.7%	-164.6	-122.4
National	1.66	1.9%	83.3%	10.4%	-343.6	-509.9

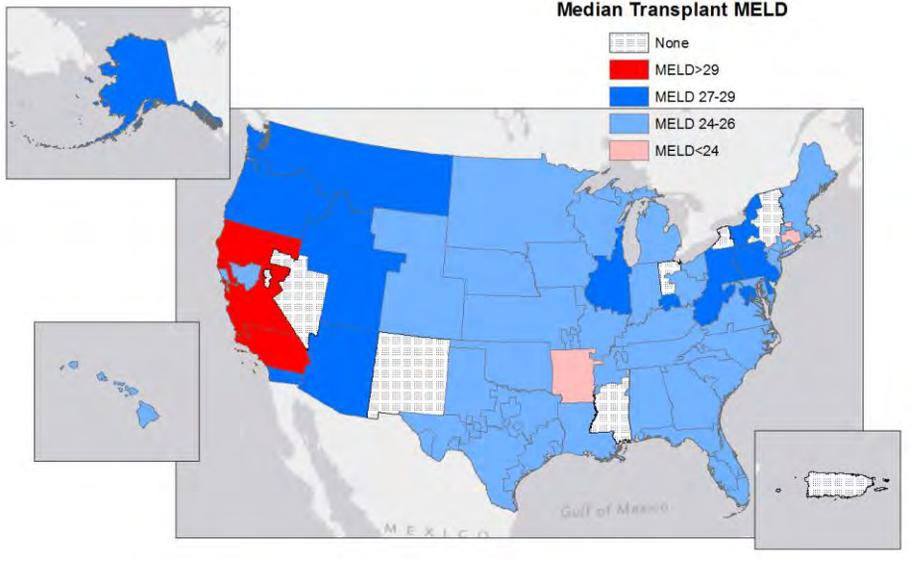
Existing geographic disparity



8 districts reduce disparity



4 districts reduce disparity



Projected organ transport impacts

Districts	% Local	% District	% National	Median distance	Median hours transport	% flying
4	26%	73%	1%	340	2.05	74%
8	40%	58%	2%	178	1.75	64%
Current	73%	23%	4%	68	1.5	44%
Regional	49%	48%	4%	137	1.7	61%
National	18%	15%	67%	768	2.9	89%

Pre-share 35: 81.6% local
 Post-share 35: 66.6% local

Gender and pediatric status

	Female	Pediatric
Share 35	35.1%	7.1%
Regional sharing	35.1%	7.3%
8 district sharing	35.2%	7.7%
4 district sharing	35.6%	8.5%

- No significant differences between these alternatives for percent female ($p=.60$)
- Significantly larger numbers of pediatric transplants ($p < .001$) with increased sharing

Ethnicity

	% white	% black	% hispanic	% other
Share 35	69.2%	10.9%	14.0%	5.9%
Regional	69.0%	10.9%	14.0%	6.1%
8 district	68.0%	11.1%	14.5%	6.3%
4 district	67.6%	11.4%	14.7%	6.3%

- No significant change for black ($p=.28$), nor for other ($p=0.08$)

Ethnicity

	% white	% black	% hispanic	% other
Share 35	69.2%	10.9%	14.0%	5.9%
Regional	69.0%	10.9%	14.0%	6.1%
8 district	68.0%	11.1%	14.5%	6.3%
4 district	67.6%	11.4%	14.7%	6.3%

- Percent of transplanted candidates who are white decreases ($p < 0.001$) while percent of transplanted candidates who are hispanic increases ($p = 0.02$)

The good news

- There are many optimized maps that would significantly reduce variance in median MELD at transplant, and also reduce waitlist deaths.
- Minority candidates are predicted to have similar or increased transplantation in the optimized maps.
- Implementing one of these redistricting maps will significantly improve geographic equity compared with either local-first allocation or regional sharing with the existing regions.