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Effect of broader geographic sharing of donor lungs on lung transplant waitlist outcomes

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KEYWORDS:
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BACKGROUND: The United States lung allocation system prioritizes allocation based on medical urgency and benefit but does not address a federal mandate for broader geographic organ sharing. It is unknown whether broader geographic sharing of donor lungs would improve lung transplant waitlist outcomes.
METHODS: A discrete event microsimulation model simulated donor lung allocation according to different geographic lung-sharing policies, including the historic local donor service area (DSA)-based policy and hypothetical policies that prioritize candidates to donors within 500-mile or 1,000-mile geographic radii. Candidate waitlist mortality, number of transplants, and 1-year survival were compared across organ allocation policies. Waitlist mortality rates were further stratified by diagnosis, Lung Allocation Score (LAS) threshold, ABO blood type, and region.
RESULTS: Under broader geographic lung sharing, the proportion of chronic obstructive pulmonary disease transplant recipients decreased, whereas the proportion of pulmonary fibrosis recipients increased. Waitlist mortality decreased with broader geographic lung sharing with a 21.3% decrease in waitlist mortality with 500-mile lung sharing and a 31.8% decrease in waitlist mortality with 1,000-mile lung sharing. The decrease in waitlist deaths occured across all U.S. geographic regions and was greatest in candidates with pulmonary fibrosis and/or high medical urgency.
CONCLUSIONS: Broader geographic sharing of donor lungs could reduce waitlist mortality, particularly among pulmonary fibrosis and high-medical-urgency candidates.
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Patients with end-stage lung disease who undergo lung transplantation have prolonged survival and improved quality of life. Given that access to transplant is limited by the supply of donor lungs, donor lungs are distributed according to national organ allocation policies.[1] In 2000, the United States Department of Health and Human Services (DHHS) mandated that cadaveric organ allocation within the U.S. occur by medical urgency while minimizing the effect of geography.[2] The Lung Allocation Score (LAS) was subsequently introduced in May 2005, which changed candidate prioritization for donor lungs from accumulated waitlist time to a numerical score based on the candidate's medical urgency and expected benefit.[3] However, this policy change did not address the geographic constraints of donor lung allocation as candidates in the same local area as a donor (donor service area, DSA) continued to receive priority over non-local DSA candidates with greater medical urgency.[4]

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Although an initial improvement in waiting list mortality was reported after implementation of the LAS, the U.S. waiting list mortality rate has increased since 2007, with studies supporting that local DSA-prioritized allocation has contributed to waitlist mortality disparities.[1,5–7] Despite low waitlist mortality and smaller net survival gains for candidates with low medical urgency, low medical urgency candidates matched to a local DSA donor comprise the majority of lung transplants within the USA.[7,8] This local DSA-based prioritization of donors to candidates within the same DSA has resulted in transplantation of less medically urgent candidates within a local DSA, while more urgent candidates within a neighboring DSA waited and frequently died.[6] Accordingly, the historic lung allocation policy that prioritizes by DSA rather than by a broader geographic area has been targeted as arbitrary and discriminatory in a lawsuit against the U.S. DHHS.[9,10] This lawsuit prompted an emergency review of lung allocation policy and implementation in November 2017 of a new allocation policy adopting a 250-mile radius from donor to candidate as the first sequence of lung allocation. The choice for a 250-mile sharing radius in allocation policy rather than broader sharing within a traditional Zone A (500-mile) or Zone B (1,000-mile) radius has been scrutinized by the lung transplant community.[10] However, broader policy changes to a 500- or 1,000-mile prioritized policy was deferred pending further examination of the impact of broader geographic lung sharing.[11]

We hypothesized that broader geographic sharing of donor lungs would reduce waitlist mortality and minimize geographic disparities by prioritizing transplant access to candidates with the greatest medical need without undue geographic limitation. We used a discrete event microsimulation model to assess the hypothesis that a lung allocation system that allows broader geographic lung sharing would reduce waitlist mortality. Understanding how potential organ allocation strategies impact waitlist and post-transplant outcomes can inform lung organ allocation policy decisions aimed at prioritizing lung transplant access to candidates with the greatest medical need.

Methods

In this study we used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, waitlisted candidates, and transplant recipients in the USA, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA) of the DHHS provides oversight of the activities of OPTN and SRTR contractors.

Lung allocation policy models

Proposed lung allocation policies were evaluated using the Thoracic Simulated Allocation Model (TSAM), a discrete event microsimulation model originally developed by the SRTR and modified for purposes of this study.[12] The allocation rules of the simulated lung allocation policies are described in detail in the Methods section and in Table S1 of the Supplementary Material (available at www.jhltonline.org/). In brief, we compared local DSA-based allocation rules that first prioritize adult donors to adult and adolescent candidates within the same DSA against allocation rules that first prioritize adult donors to all adult and adolescent candidates within 500- or 1,000-mile radii. The models allocated adolescent and pediatric donor lungs in broader geographic sharing models according to recently suggested allocation rules for this population.[13] Additional allocation models that prioritized 500- or 1,000-mile donor lung sharing only to adult or adolescent candidates with high medical urgency, as defined by a LAS ≥ 50, were performed and compared with the other allocation models (refer to Supplementary Material online).

Study population and microsimulation model

Candidates on the waitlist and all deceased donors between July 1, 2009 and June 30, 2011 were imputed into the discrete event microsimulation model and maintained in a time-ordered queue that reflected the historic candidates' listing date. Donor and candidate matching was done using the allocation rules specified in the online Methods section and Table S1. Acceptance of donor-candidate matches was based on a predictive model of historic donor lung acceptance constructed on donor characteristics, recipient–donor match characteristics, and use of a random number generator. A random number was produced between 0 and 1 and compared with the expected probability of lung acceptance, with a lower random number resulting in donor lung acceptance. Candidates who became active on the waitlist had either an actual historic time to death or waitlist removal, or, for candidates who had historically undergone lung transplant, an estimated time to waitlist death or removal was calculated. The time to waitlist death or removal was estimated by matching the candidate to another candidate with similar baseline listing characteristics and a non-transplant removal event. A multivariable Cox proportional hazard model was used to estimate 1-year post-transplant survival for each transplant candidate. Historic donors within this time period were offered in 10 varying orders: the original order and 9 other random orders to simulate the real-world variation in donor arrival. We performed a total of 100 model simulations, 10 iterations of each of the 10 donor orders, to assess the robustness of each allocation model given the expected real-world variations in donors, organ acceptance, and expected survival.

We calculated candidate waitlist deaths, transplants, and mortality rate for each of the 100 model iterations and reported the median and interquartile range (IQR) of each lung allocation model. We calculated waitlist mortality rate by dividing the number of estimated deaths by the cumulative waitlist time of all candidates. We further stratified waitlist mortality rates by candidate diagnosis, LAS threshold, ABO blood type, and OPTN region for each allocation model. We compared expected 1-year survival across the allocation models. Similar to previous TSAM methodology, formal testing of the statistical significance between model outcomes was not performed due to the presence of the same candidates within each lung allocation model and within multiple model iterations.[13]

We compared simulated model events to historic waitlist events by computing the actual waitlist mortality rate and transplant recipient characteristics from July 1, 2009 to June 30, 2011 using the SRTR standard analysis files. Actual candidates on the lung transplant waitlist during this period were identified, waitlist time calculated, and their waitlist outcome, including death or

transplant, was recorded. We excluded candidates listed for re-transplant or multiorgan transplant.

Results

Recipients' characteristics

There were a total of 6,538 candidates actively listed for lung transplantation between July 1, 2009 and June 30, 2011. Transplant recipient characteristics by historic cohort and by each simulated allocation model are shown in Table 1 and Table S2 (online). As compared with the DSA-based allocation system, allocation models with broader geographic lung sharing had a smaller proportion of chronic obstructive pulmonary disease (Group A) recipients and a larger proportion of pulmonary fibrosis (Group D) recipients. Pulmonary hypertension (Group B) and cystic fibrosis (Group C) recipients increased slightly under overall broader geographic lung sharing. Recipient LAS at transplant and the proportion of recipients hospitalized or on mechanical ventilation or extracorporeal membrane oxygenation life support before transplant increased with broader geographic lung sharing. There was an increase in the number of children and adolescents transplanted with broader geographic lung sharing. The distance between the recipient and donor and the proportion of non-local donors increased with broader geographic lung sharing, but less so with broader geographic lung sharing based on LAS threshold (see Table S2 online).

Waitlist deaths and transplants

The number of waitlist candidate deaths decreased by 20% to 30%, with broader geographic sharing of donor lungs (Table 2). The estimated median number of waitlist deaths was 588 (interquartile range [IQR] 581 to 596) under the DSA-based allocation rules, with a 21.3% decrease in waitlist deaths with 500-mile lung sharing (462 deaths, IQR 457 to 468) and a 31.8% decrease in waitlist deaths with 1,000-mile lung sharing (402 deaths, IQR 396 to 406). As compared with the 500- and 1,000-mile lung-sharing models, the allocation

Table 1 Recipients' Characteristics by Historic and Simulated Donor Lung Allocation Models

	Historic cohort ($n = 3,482$)	Donor service area–based lung-sharing model ($n = 347,843$)[a]	500-mile lung-sharing model ($n = 350,208$)*	1,000-mile lung-sharing model ($n = 348,060$)[a]
Age	53.3 ± 15.5	53.3 ± 15.6	52.8 ± 16.2	52.7 ± 16.3
Male gender	2,034 (58.4%)	192,393 (55.3%)	194,724 (55.6%)	194,023 (55.5%)
Child	44 (1.3%)	5,667 (1.6%)	6,210 (1.8%)	6,186 (1.8%)
Adolescent	67 (1.9%)	8,568 (2.5%)	10,769 (3.1%)	10,850 (3.1%)
Adult	3,371 (96.8%)	333,608 (95.9%)	333,229 (95.2%)	332,844 (95.1%)
Race/ethnicity				
Non-Hispanic white	2,903 (83.4%)	282,940 (82.0%)	281,202 (80.9%)	279,162 (80.4%)
Non-Hispanic black	295 (8.5%)	34,147 (9.9%)	34,961 (10.1%)	35,142 (10.1%)
Hispanic	201 (5.8%)	21,622 (6.3%)	24,129 (6.9%)	24,934 (7.2%)
Asian	52 (1.5%)	6,526 (1.9%)	7,255 (2.1%)	7,867 (2.3%)
Lung disease type[b]				
Group A	990 (28.5%)	97,257 (28.0%)	70,697 (20.2%)	61,956 (17.7%)
Group B	157 (4.5%)	16,302 (4.7%)	19,572 (5.6%)	19,806 (5.7%)
Group C	458 (13.2%)	46,421 (13.4%)	51,206 (14.6%)	51,804 (14.8%)
Group D	1,867 (53.8%)	182,196 (52.4%)	202,523 (57.8%)	210,128 (60.1%)
Pre-transplant condition				
Hospitalized	419 (14.4%)	39,950 (11.5%)	45,841 (13.1%)	48,909 (14.0%)
Ventilator use	130 (3.7%)	16,273 (4.7%)	20,189 (5.8%)	22,314 (6.4%)
ECMO use	22 (0.6%)	1,750 (0.5%)	2,044 (0.6%)	2,158 (0.6%)
LAS	47.7 ± 17.9	46.8 ± 16.5	48.9 ± 16.3	49.9 ± 16.4
Geographic miles between donor and recipient	—	202.9 ± 276.8	321.3 ± 251.1	542.1 ± 302.4
Geographic zone of donor and recipient				
Local DSA	—	208,097 (59.82)	45,873 (13.10)	20,696 (5.92)
500 miles	—	117,254 (33.71)	276,258 (78.88)	133,716 (38.22)
1,000 miles	—	15,282 (4.39)	4,892 (1.40)	189,210 (54.08)

Data expressed as mean ± standard deviation or as number (%). DSA, donor service area; ECMO, extracorporeal membrane oxygenation; LAS, Lung Allocation Score.

[a]Represents the total number of recipients from all 100 model iterations.

[b]Group A represents candidates with obstructive lung disease; Group B represents candidates with pulmonary vascular disease; Group C represents candidates with cystic fibrosis or bronchiectasis; and Group D represents candidates with pulmonary fibrosis or restrictive lung disease.

Table 2 Waitlist and Transplant Outcomes by Simulated Donor Lung Allocation Models

	DSA-based lung sharing	500-mile lung sharing	1,000-mile lung sharing
Waitlist deaths[a]	588 (581 to 596)	462 (457 to 468)	402 (396 to 406)
Relative percent change in deaths	Reference	−21.3%	−31.8%
Waitlist mortality rate[b]	17.1 (16.8 to 17.3)	12.9 (12.7 to 13.1)	11.0 (10.9 to 11.1)
Transplant recipients[a]	3,479 (3,472 to 3,487)	3,502 (3,496 to 3,509)	3,499 (3,494 to 3,504)
Disease-specific waitlist mortality rates[b,c]			
Group A	9.0 (8.7 to 9.1)	8.1 (8.0 to 8.2)	7.6 (7.5 to 7.8)
Group B	18.6 (18.0 to 19.2)	16.7 (16.1 to 17.1)	16.5 (16.1 to 17.0)
Group C	20.7 (19.8 to 21.3)	14.6 (14.1 to 15.6)	11.9 (11.5 to 12.4)
Group D	28.8 (28.1 to 29.5)	21.1 (20.5 to 22.0)	15.9 (15.5 to 16.4)
LAS waitlist mortality rates[b]			
LAS <35	8.8 (8.6 to 8.9)	8.1 (8.0 to 8.1)	7.8 (7.8 to 7.9)
LAS 35 to 39	12.4 (11.9 to 12.8)	12.9 (12.6 to 13.3)	13.5 (13.2 to 13.8)
LAS 40 to 49	18.7 (18.0 to 19.3)	13.4 (12.6 to 14.1)	11.0 (10.5 to 11.5)
LAS ≥ 50	93.8 (89.4 to 98.5)	77.0 (72.5 to 80.4)	51.5 (48.2 to 54.7)
ABO blood type waitlist mortality rates[b]			
Blood Type A	16.5 (16.1 to 16.9)	12.0 (11.7 to 12.3)	10.0 (9.8 to 10.2)
Blood Type B	20.9 (20.1 to 21.7)	17.1 (16.3 to 17.9)	13.5 (12.7 to 14.1)
Blood Type AB	29.6 (27.8 to 31.9)	26.4 (24.7 to 28.8)	21.8 (20.4 to 23.6)
Blood Type O	16.0 (15.7 to 16.3)	11.9 (11.8 to 12.2)	10.5 (10.3 to 10.7)
Post-transplant survival[a]			
Predicted 30-day survival	95.4% (95.2% to 95.6%)	95.2% (95.0% to 95.4%)	95.2% (95.0% to 95.4%)
Predicted 1-year survival	82.2% (81.8% to 82.6%)	81.4% (81.1% to 82.0%)	81.0% (80.6% to 81.4%)

DSA, donor service area; LAS, Lung Allocation Score.
[a]Reported as median (interquartile range).
[b]Rates reported as median deaths per 100 waitlist-years (interquartile range).
[c]Group A represents candidates with obstructive lung disease; Group B represents candidates with pulmonary vascular disease; Group C represents candidates with cystic fibrosis or bronchiectasis; and Group D represents candidates with pulmonary fibrosis or restrictive lung disease.

models allowing 500-mile or 1,000-mile lung sharing only for LAS ≥ 50 candidates estimated a comparable decrease in waitlist deaths (see Table S3 online). The median (IQR) number of transplant recipients under DSA-based lung sharing was 3,479 (IQR 3,472 to 3,487), with a similar number of transplants with broader lung sharing. There were 3,502 recipients (IQR 3,496 to 3,509) under 500-mile lung sharing and 3,499 recipients (IQR 3,494 to 3,504) under 1,000-mile lung sharing (Table 2).

Waitlist mortality rate

The actual historic waitlist mortality rate from the study period was 16.4 deaths per 100 waitlist-years. The estimated waitlist mortality rate under the DSA-based allocation rules was 17.1 deaths per 100 waitlist-years (IQR 16.8 to 17.3) with a decrease to 12.9 deaths per 100 waitlist-years (IQR 12.7 to 13.1) with 500-mile lung sharing and 11.0 deaths per 100 waitlist-years (IQR 10.9 to 11.1) with 1,000-mile lung sharing (Figure 1). Similarly, there were an estimated 13.0 deaths per 100 waitlist-years (IQR 12.8 to 13.1) with 500-mile lung sharing for LAS ≥ 50 candidates and 11.5 deaths per 100 waitlist-years (IQR 11.4 to 11.7) with 1,000-mile lung sharing for LAS ≥ 50 candidates (see Figure S1 online).

The impact of broader geographic sharing of lungs on waitlist mortality rate varied by candidate lung diagnosis; however, when compared with DSA-based donor lung sharing, candidates in all disease groups had a decrease in waitlist mortality rate with broader donor lung sharing (Figure 2 and Table 2, and Figure S2 and Table S3 online). The greatest difference in waitlist mortality was seen within pulmonary fibrosis candidates. Waitlist mortality rates decreased the most in candidates with the greatest medical urgency, as defined by LAS ≥ 50 (Figure 3 and Table 2, and Figure S3 and Table S3 online). Waitlist mortality rates decreased across all ABO blood types (Table 2, and Table S3 online). Waitlist mortality rates also decreased in all OPTN regions with broader geographic lung sharing (see Table S4 online). There was an absolute decrease in regional waitlist mortality, as compared with the DSA-based allocation policy, of 0.1 to 7.1 deaths per 100 waitlist-years with 500-mile lung sharing and of 3.3 to 9.2 deaths per 100 waitlist-years with 1,000-mile lung sharing (Figure 4).

Post-transplant survival

There was a slight difference in early and 1-year post-transplant survival with broader geographic lung sharing (Table 2). The estimated median (IQR) 30-day survival was 95.4% (95.2% to 95.6%) under DSA-based allocation rules, 95.2% (95.0% to 95.4%) under 500-mile lung-sharing rules, and 95.2% (95.0% to 95.4%) under 1,000-mile lung-sharing rules. The estimated median

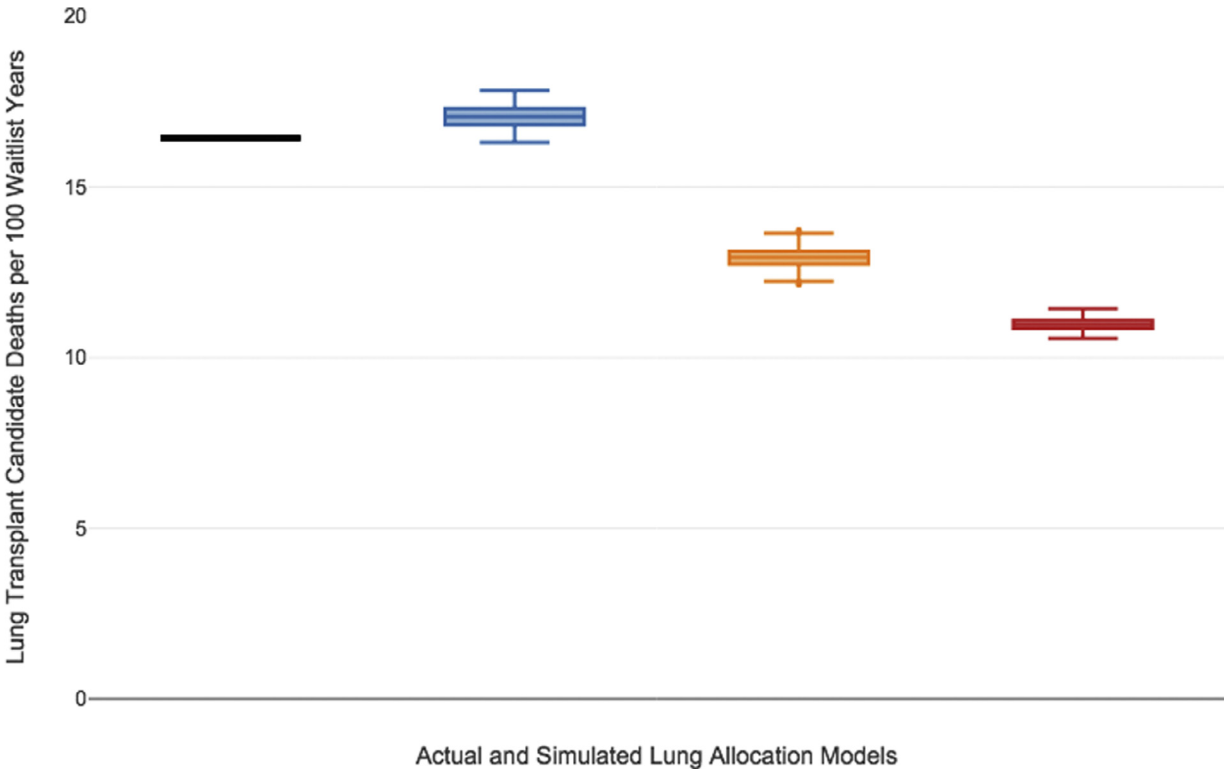

Figure 1 Waitlist mortality rate. Box-and-whisker plots of the estimated waitlist mortality rate (deaths per 100 waitlist-years) for the DSA-based allocation model (blue boxplot), 500-mile lung-sharing model (orange boxplot), and the 1,000-mile lung-sharing model (red boxplot) as compared with the historic waitlist mortality rate (black line). The horizontal line within the box indicates the median, the box signifies the interquartile range (IQR), whiskers identify the lowest and highest data within 1.5 times the IQR, and dots identify any outliers.

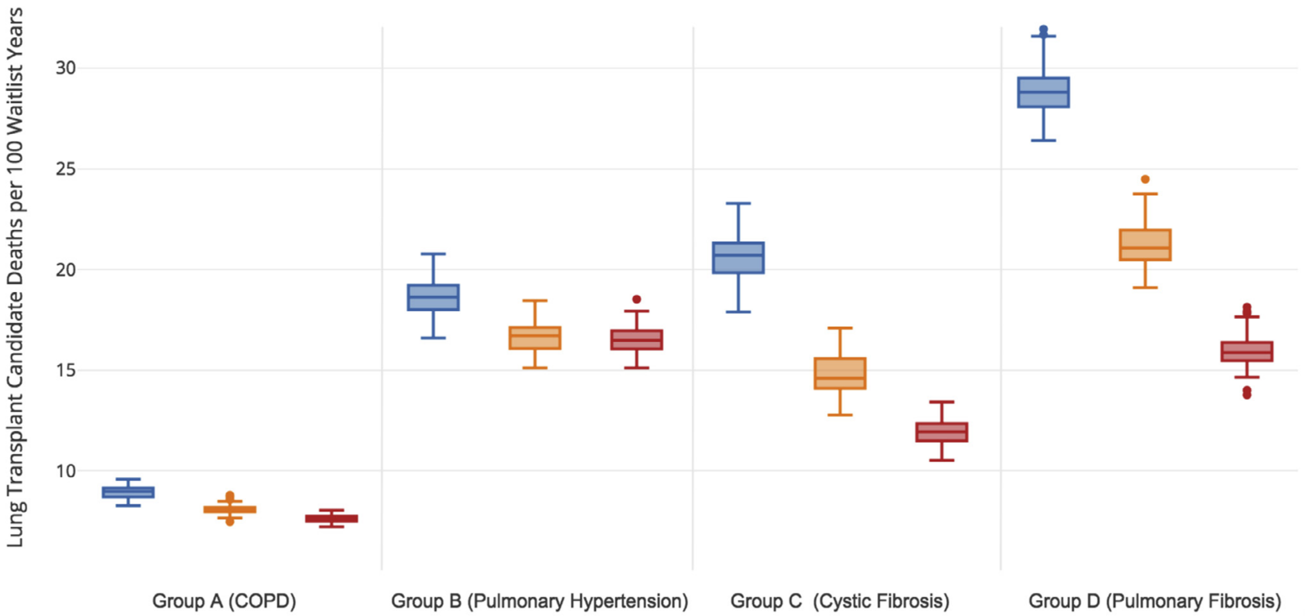

Figure 2 Waitlist mortality rate by lung diagnosis. Box-and-whisker plots of the estimated waitlist mortality rate (deaths per 100 waitlist-years) by candidate lung diagnosis for the DSA-based allocation model (blue boxplot), 500-mile lung-sharing model (orange boxplot), and the 1,000-mile lung-sharing model (red boxplot). The horizontal line within the box indicates the median, the box signifies the interquartile range (IQR), whiskers identify the lowest and highest data within 1.5 times the IQR, and dots identify any outliers.

(IQR) 1-year survival was 82.2% (81.8% to 82.6%) under DSA-based allocation rules, 81.4% (81.1% to 82.0%) under 500-mile lung-sharing rules, and 81.0% (80.6% to 81.4%) under 1,000-mile lung-sharing rules. The estimated median (IQR) 30-day and 1-year survival rates under 500-mile lung sharing for LAS ≥ 50 candidates and 1,000-mile lung sharing for LAS ≥ 50 candidates are shown in Table S3 (online).

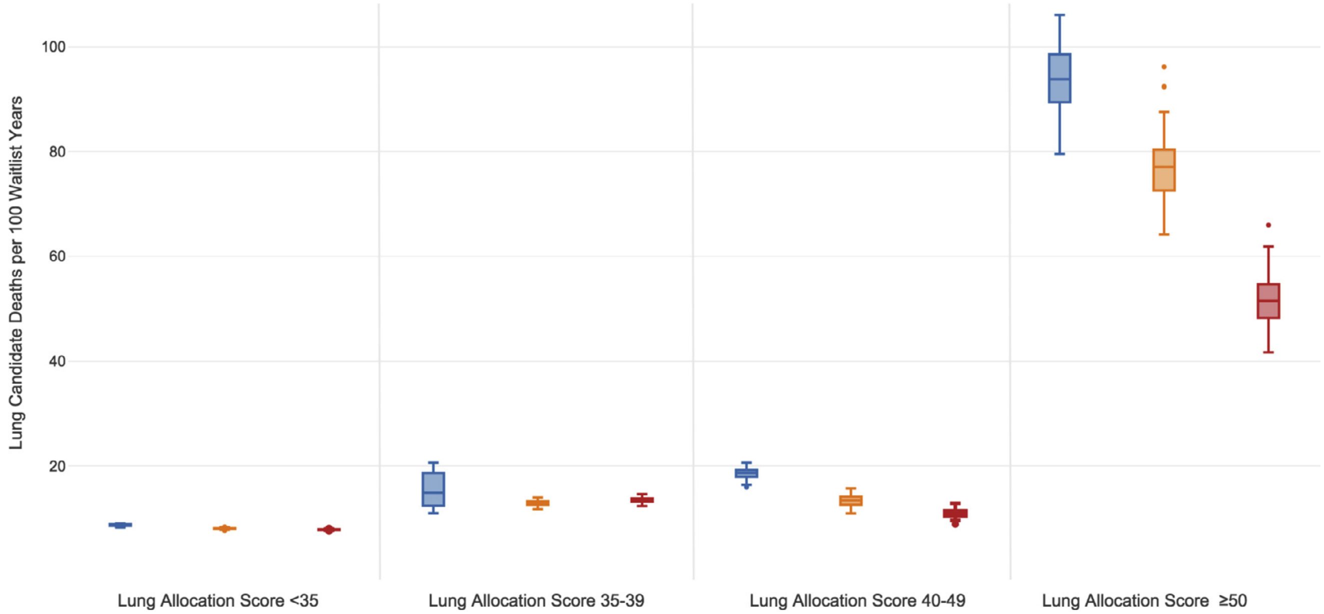

Figure 3 Waitlist mortality rate by Lung Allocation Score (LAS). Box-and-whisker plots of the estimated waitlist mortality rate (deaths per 100 waitlist-years) by candidate LAS threshold for the DSA-based allocation model (blue boxplot), 500-mile lung-sharing model (orange boxplot), and the 1,000-mile lung-sharing model (red boxplot). The horizontal line within the box indicates the median, the box signifies the interquartile range (IQR), whiskers identify the lowest and highest data within 1.5 times the IQR, and dots identify any outliers.

Discussion

Broader geographic lung sharing could decrease waitlist mortality across all candidate diagnoses and U.S. transplant regions without impacting the number of transplants performed. Broader geographic lung sharing could increase the proportion of pulmonary fibrosis transplant recipients, and reduce the high waitlist mortality rate for candidates with pulmonary fibrosis to rates similar to those in other advanced lung disease diagnoses. Patients with a high LAS threshold, which indicates a greater transplant urgency, would receive the greatest reduction in waitlist mortality under broader geographic lung sharing. These findings are in concordance with the DHHS Final Rule to allocate donor lungs to those with greatest medical urgency while minimizing the effect of geography.[2]

Within U.S. solid-organ transplant allocation policy, there has been a shift toward broader geographic sharing of donor organs to candidates with greater medical urgency. Liver and heart allocation rules have adopted broader geographic sharing of donor organs to candidates with higher illness severity in attempts to reduce waitlist deaths.[4] A 2006 change in heart allocation policy that involved regional sharing of heart organs to candidates with the greatest level of medical urgency successfully decreased waitlist mortality and resulted in more medically urgent candidates receiving heart transplantation without worsening 1-year post-transplant survival.[14,15] In June 2013, the Share 35 policy was implemented for U.S. liver allocation, which broadened donor liver prioritization to all regional candidates with a model for end-stage liver disease (MELD) score of ≥ 35. This policy resulted in decreased waitlist mortality, particularly among those with a high MELD score, without changing early post-transplant survival.[16,17] Similarly, our results suggest that a policy of broader donor lung sharing by any of the simulated models would decrease waitlist mortality, particularly waitlist mortality for candidates with a high LAS.

The arguments against broader lung sharing include the concern for increased lung ischemia time with longer travel distances, increased transplant of more medically urgent patients resulting in worse post-transplant survival, economic implications, and apprehension from community organizations and/or transplant programs regarding its effect on community donation and individual center volume.[18] Although the acceptable duration of donor lung ischemia remains controversial, 2 recent U.S. transplant registry analyses demonstrated no association between prolonged ischemia times, defined as >6 hours, with primary graft dysfunction or survival, particularly at high-volume centers.[19,20] The distance between the donor and transplant center increased with modeling broader geographic lung sharing, likely resulting in an increase in ischemia time; however, the geographic sharing radii of 500 miles and 1,000 miles would allow for generally acceptable ischemia times. Importantly, the lung allocation models that simulated broader lung sharing only for candidates with high medical urgency (LAS ≥ 50) had a less significant impact on travel distance or proportion of imported donors, while having a comparable effect on reducing waitlist mortality.

We have demonstrated that broader geographic lung sharing could increase the overall illness severity of lung transplant candidates and may influence 1-year post-transplant survival. Given the small magnitude of predicted change in post-transplant survival, the clinical significance of these changes is unclear. Using the model outputs, we

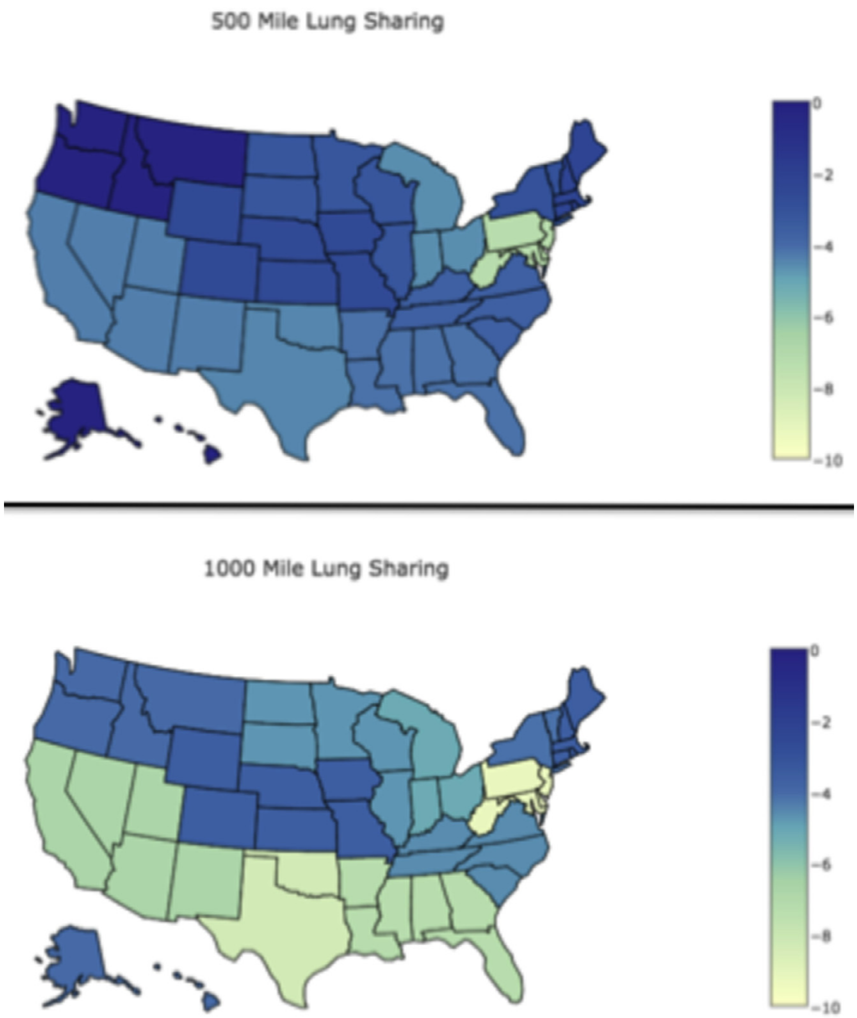

Figure 4 Waitlist mortality rate change within each Organ Procurement and Transplantation Network (OPTN) region. A choropleth map of individual states displays the absolute reduction in waitlist mortality rate (deaths per 100 waitlist-years) by OPTN region under each broader geographic sharing model as compared with the local donor service area–based model. Individual states were given the overall change seen within their assigned OPTN region.

performed "back-of-the-envelope" calculations of the number of lives saved on the waiting list and number of lives lost at 1 year post-transplant; these calculations suggest approximately 95 net lives saved under the 500-mile lung-sharing models and 130 to 140 net lives saved under the 1,000-mile lung-sharing models. As these calculations are based on the models prediction of both waitlist deaths and 1-year post-transplant deaths, they may be influenced by the model limitations described below. It is noteworthy that, despite an increase in candidate illness severity after a previous revision in lung allocation policy, the overall early or 1-year post-transplant survival did not change.[21–23]

As previous allocation policy changes have been associated with increased post-transplant health-care resource use, the economic implications of broader geographic lung sharing deserve further attention.[24] These economic analyses should account for the impact of longer travel distances and organ import and export costs in addition to potential cost-savings from reducing the considerable pre-transplant cost of some high-illness-severity candidates. Modeling of the economic impact of broader liver sharing has suggested overall cost-effectiveness, although it did not include increases in import and export organ procurement costs.[25,26]

Like preceding allocation models, our model has several limitations. The model is built and simulated upon historic lung transplant data from 2009 to 2011, and, given continued changes in the lung transplant candidate population, allocation policy changes may have different effects on waitlist candidates and recipients in the present era. For instance, registry reports have demonstrated that, from 2011 to 2016, the proportion of waitlisted candidates ≥ 65 years old has increased from 17.6% to 23.9% and Group D candidates increased from 31.8% to 37.9%.[27] In addition, there has been a revision to LAS calculation in 2015, which may impact specific diagnosis groups, such as pulmonary hypertension. Second, the model does not allow for center-level variation in the likelihood of donor acceptance and recipient survival. It assumes similar lung acceptance thresholds across all transplant centers. Due to this limitation and the relatively small number of candidates at some centers, the model does not reliably measure the individual center-level impact of broader geographic lung sharing. Finally, the

TSAM allows for simulation of organ sharing within historic geographic thresholds of 500, 1,000, 1,500, 2,500, and >2,500 miles, but it does not support simulation using shorter geographic distances, such as the recently instituted 250-mile threshold. Despite the aforementioned model limitations there is a precedent for use of similar simulated allocation models within liver, kidney, heart, and pediatric lung transplantation to guide organ allocation policy decisions.[12] The SRTR liver simulated allocation model has been used to study the effect of geographic redistricting and regional sharing allocation policies on geographic disparity and waitlist mortality within liver transplantation.[28,29] Within pediatric lung transplantation, the TSAM was used to simulate different allocation strategies that improve pediatric access to lung transplant.[13]

In conclusion, the lung allocation system that prioritizes lung allocation to a recipient within the same donor service area (DSA) contributes to geographic waitlist disparities and is inconsistent with the DHHS Final Rule to prioritize donor organs to those of greatest medical urgency while minimizing the effect of geography. Lung allocation policies that allow broader geographic lung sharing would likely decrease waitlist mortality without impacting the number of transplants performed. The reduction in waitlist mortality with broader geographic lung sharing would be seen across the U.S. and would have the greatest impact on candidates with high medical urgency.

Disclosure statement

The authors have no relevant conflicts of interest to disclose. The data reported herein have been supplied by the Minneapolis Medical Research Foundation (MMRF) as the contractor for the Scientific Registry of Transplant Recipients (SRTR). The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation by the SRTR or the U.S. Government.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.1016/j.healun.2018.09.007.

References

1. Valapour M, Skeans MA, Smith JM, et al. Lung. Am J Transplant 2016;16(suppl 2):141-68.
2. Department of Health and Human Services. Organ Procurement and Transplantation Network; Final Rule. Fed Reg 42 CFR, Part 121 1999;64:56650-1.
3. Egan TM, Murray S, Bustami RT, et al. Development of the new lung allocation system in the United States. Am J Transplant 2006;6:1212-27.
4. Colvin-Adams M, Valapour M, Hertz M, et al. Lung and heart allocation in the United States. Am J Transplant 2012;12:3213-34.
5. Benvenuto LJ, Anderson DR, Kim HP, et al. Geographic disparities in donor lung supply and lung transplant waitlist outcomes: a cohort study. Am J Transplant 2018;18:1471-80.
6. Russo MJ, Meltzer D, Merlo A, et al. Local allocation of lung donors results in transplanting lungs in lower priority transplant recipients. Ann Thorac Surg 2013;95:1231-4.
7. Iribarne A, Meltzer DO, Chauhan D, et al. Distribution of donor lungs in the United States: a case for broader geographic sharing. Clin Transplant 2016;30:688-93.
8. Russo MJ, Worku B, Iribarne A, et al. Does lung allocation score maximize survival benefit from lung transplantation? J Thorac Cardiovasc Surg 2011;141:1270-7.
9. HHS adopts new transplant policy after patient desperate for lung sues. Available at: https://www.law.com/newyorklawjournal/sites/newyorklawjournal/ 2017/11/ 29/ hhs-adopts-new-transplant-policy-after-patient-desperate-for-lung-sues/. Accessed: December 4, 2017.
10. Egan TM. From 6 years to 5 days for organ allocation policy change. J Heart Lung Transplant 2018;37:675-7.
11. Organ Procurement and Transplantation Network (OPTN) Executive Committee. Broader sharing of adult donor lungs. Available at: https://optn.transplant.hrsa.gov/media/2314/broader_sharing_lungs_20171124.pdf/. Accessed: December 4, 2017.
12. Thompson D, Waisanen L, Wolfe R, et al. Simulating the allocation of organs for transplantation. Health Care Manage Sci 2004;7:331-8.
13. Tsuang WM, Chan KM, Skeans MA, et al. broader geographic sharing of pediatric donor lungs improves pediatric access to transplant. Am J Transplant 2016;16:930-7.
14. Schulze PC, Kitada S, Clerkin K, et al. Regional differences in recipient waitlist time and pre- and post-transplant mortality after the 2006 United Network for Organ Sharing policy changes in the donor heart allocation algorithm. JACC Heart Fail 2014;2:166-77.
15. Singh TP, Almond CS, Taylor DO, et al. Decline in heart transplant wait list mortality in the United States following broader regional sharing of donor hearts. Circ Heart Fail 2012;5:249-58.
16. Massie AB, Chow EKH, Wickliffe CE, et al. early changes in liver distribution following implementation of Share 35. Am J Transplant 2015;15:659-67.
17. Edwards EB, Harper AM, Hirose R, et al. The impact of broader regional sharing of livers: 2-year results of "Share 35". Liver Transplant 2016;22:399-409.
18. Ubel PA. Transplantation traffic—geography as destiny for transplant candidates. New Engl J Med 2014;371:2450-2.
19. Grimm JC, Valero 3rd V, Kilic A, et al. Association between prolonged graft ischemia and primary graft failure or survival following lung transplantation. JAMA Surg 2015;150:547-53.
20. Hayes Jr D, Hartwig MG, Tobias JD, et al. Lung transplant center volume ameliorates adverse influence of prolonged ischemic time on mortality. Am J Transplant 2017;17:218-26.
21. McCue JD, Mooney J, Quail J, et al. Ninety-day mortality and major complications are not affected by use of lung allocation score. J Heart Lung Transplant 2008;27:192-6.
22. Merlo CA, Weiss ES, Orens JB, et al. Impact of U.S. Lung Allocation Score on survival after lung transplantation. J Heart Lung Transplant 2009;28:769-75.
23. Maxwell BG, Levitt JE, Goldstein BA, et al. Impact of the lung allocation score on survival beyond 1 year. Am J Transplant 2014;14:2288-94.
24. Maxwell BG, Mooney JJ, Lee PH, et al. Increased resource utilization in lung transplant admissions in the lung allocation score era. Am J Respir Crit Care Med 2015;191:302-8.
25. Fernandez H, Weber J, Barnes K, et al. Financial impact of liver sharing and organ procurement organizations' experience with share 35: implications for national broader sharing. Am J Transplant 2016;16:287-91.

26. Axelrod DA, Gheorghian A, Schnitzler MA, et al. The economic implications of broader sharing of liver allografts. Am J Transplant 2011;11:798-807.
27. Valapour M, Lehr CJ, Skeans MA, et al. OPTN/SRTR 2016 annual data report: lung. Am J Transplant 2018;18:363-433.
28. Gentry SE, Chow EK, Dzebisashvili N, et al. The impact of redistricting proposals on health care expenditures for liver transplant candidates and recipients. Am J Transplant 2016;16:583-93.
29. Washburn K, Pomfret E, Roberts J. Liver allocation and distribution: possible next steps. Liver Transplant 2011;17:1005-12.