PERSPECTIVE

Impact and Implications following the November 2017 Emergency Change to the United States Lung Allocation Policy

Maeve G. MacMurdo[1] and Stuart C. Sweet[2]

[1]Respiratory Institute, Cleveland Clinic, Cleveland, Ohio; and [2]Department of Pediatrics, Washington University, St. Louis, Missouri

ORCID IDs: 0000-0002-0232-3263 (M.G.M.); 0000-0002-0638-2586 (S.C.S.).

In the United States, the demand for donor lungs exceeds supply. Each year more than 300 patients on the waiting list die or are removed because they are too sick (1). Maximizing utility from transplant while equitably allocating donor lungs has been priority for transplant medicine since the first successful lung transplant (2, 3).

In November 2017, a lawsuit in New York set in motion a sequence of events that led to an unprecedented change in lung allocation policy. Here we discuss the lawsuit, the impact on transplant outcomes since the policy implementation, and future implications for lung transplant.

History of Lung Allocation

Allocation and distribution of donor lungs has evolved over time (4, 5). Initially, allocation was based on waiting time, with distribution prioritized to recipients within the same donation service area (DSA) as the donor, incentivizing early listing and precluding transplantation for patients with rapidly progressive disease.

In 1999 the, U.S. Department of Health and Human Services (HHS) adopted a "final rule," mandating that the Organ Procurement and Transplantation Network (OPTN) transition toward a need-based allocation system and work to reduce geographic disparities in access to donor organs (6). In response, the OPTN and the Scientific Registry for Transplant Recipients developed the lung allocation score (LAS) (7, 8). The LAS aimed to address deficiencies in the existing waitlist system by prioritizing medical urgency, while avoiding transplant in patients unlikely to derive a survival benefit.

By transplanting more patients with higher predicted transplant benefit (i.e., patients with interstitial lung disease) and fewer patients with lower predicted benefit (i.e., those with chronic obstructive pulmonary disease) a significant reduction in waitlist mortality was observed after LAS implementation in 2005. The LAS also made transplant accessible for critically ill patients who would not have survived before the LAS. Although severity of illness at time of transplant increased, there was no significant impact on post-transplant mortality (7–11). A significant increase in transplant cost and post-transplant length of stay was noted, however (10, 12).

DSA as the initial unit for lung distribution remained an area of concern. The geographic boundaries making up each DSA were initially established in the late 1980s, when Organ Procurement Organizations were established to identify potential organ donors and coordinate organ procurement and transplantation with local transplant centers. As a result, the 58 DSAs within the United States vary widely in terms of size and population density (5) (Figure 1). Before 2017, donor lungs were offered to all matching recipients within the donor's DSA before recipients outside the DSA. In March 2017, in response to a request from the HHS secretary, local DSA was removed from initial distribution of pediatric lung donors to facilitate greater access for pediatric candidates (13). For adult patients, the first distribution unit remained the DSA.

Significant discrepancies in mean LAS at transplant and time to transplant were noted among DSAs, suggesting that the geographic restriction by DSAs exacerbated variations in Organ Procurement Organization performance and donor offer acceptance (14–16). Alterations in geographic distribution of donor organs had been successfully implemented in other organ systems, and similar changes had been considered by the OPTN Thoracic Committee in 2009 (although ultimately abandoned because modeling predicted increased organ discard rates, presumably related to logistics and potential for increased ischemic time).

The Lawsuit

In November of 2017, Miriam Holman, a 21-year-old patient with severe pulmonary

(Received in original form November 3, 2019; accepted in final form February 13, 2020)

Correspondence and requests for reprints should be addressed to Stuart C. Sweet, M.D., Ph.D., Department of Pediatrics, Division of Allergy, Immunology and Pulmonary Medicine, Washington University School of Medicine, Campus Box 8116-NWT, One Children's Place, St. Louis, MO 63110. E-mail: sweet@kids.wustl.edu.

Ann Am Thorac Soc Vol 17, No 7, pp 795–799, Jul 2020

DOI: 10.1513/AnnalsATS.201911-818PS
Internet address: www.atsjournals.org

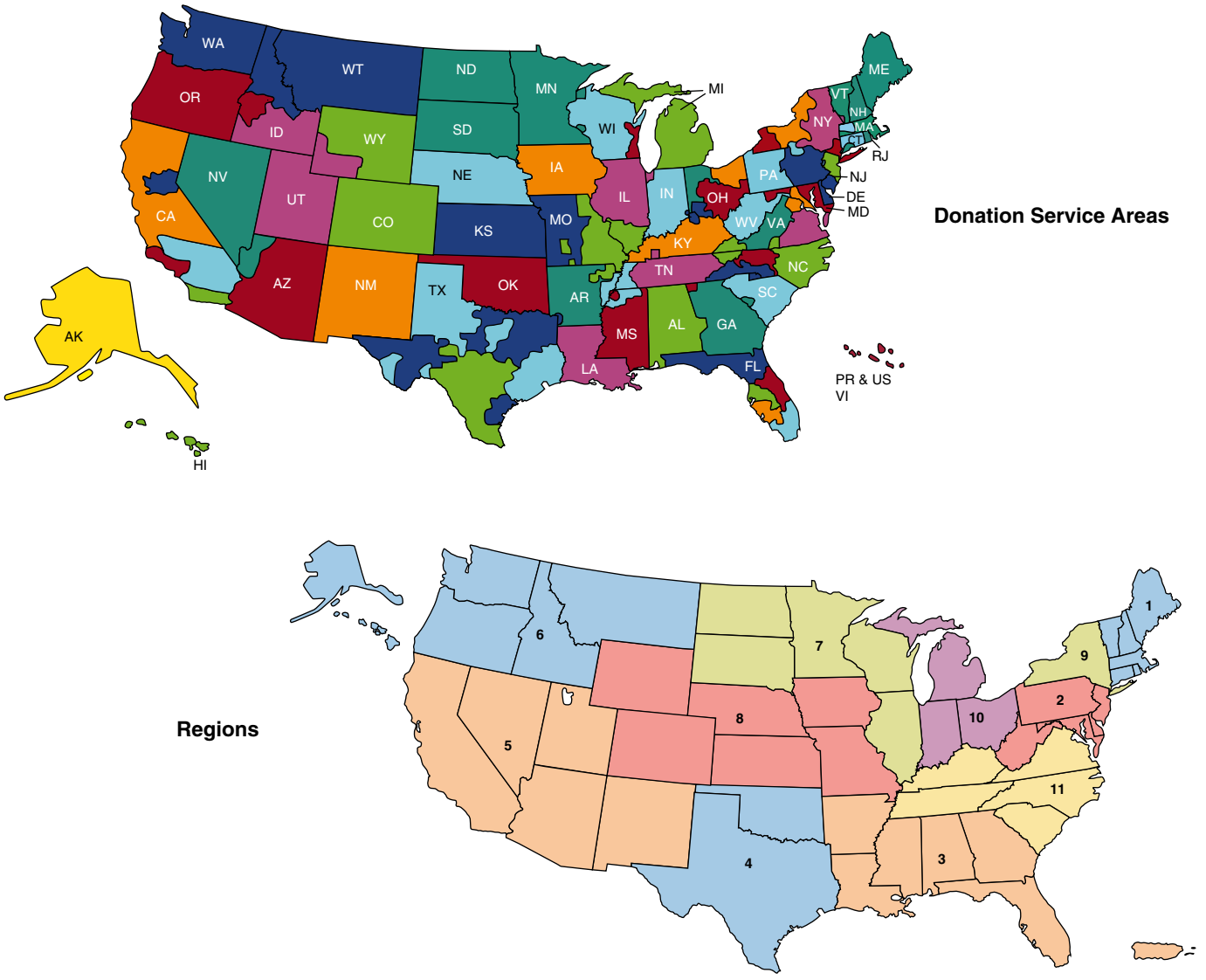

Figure 1. Distribution of the 58 donation service areas and 11 Organ Procurement and Transplantation Network regions in the United States. Reprint by permission from Reference 36.

arterial hypertension, was listed for lung transplant at Columbia University Medical Center (17). She was admitted to the intensive care unit in tenuous condition. Her LAS was greater than 90 (range, 0–100). Without transplant, her likelihood of mortality approached 100%. Recognizing that the relative scarcity of matching blood type donors within her DSA severely limited the chances of obtaining a transplant in time to prevent death, a "critical comments" letter was sent on Miriam's behalf to the HHS Secretary on November 16, 2017, requesting that he "take immediate action and direct the OPTN to set aside those portions of OPTN Policy 10 that require donor lungs to first be made available to candidates within the OPTN's local DSAs" (18). When the Secretary did not act, a lawsuit was filed, arguing that use of DSA as a method of lung allocation was discriminatory and in violation of the 1999 OPTN Final Rule (17, 18). The plaintiffs requested a temporary restraining order for emergency relief that would remove DSA from lung distribution, making the initial distribution unit a 500–nautical mile (nm) circle centered at the donor hospital.

The 1999 OPTN Final Rule states that organ distribution "shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." Although limiting geographic allocation to prevent donor organ injury was considered allowable, significant discrepancies in DSA size, shape, and population limited this argument (19, 20).

Although the court did not issue a temporary restraining order, it directed HHS to conduct an emergency review of lung policy. HHS asked the OPTN whether the use of DSA in lung allocation is *1*) consistent with the Final Rule, and *2*) more compliant than a policy with an initial distribution a 500-nm circle. The OPTN concluded that the existing policy contained

an overreliance on DSA as primary unit of allocation and opined that a revised policy without DSA is more consistent with the Final Rule. The HHS Secretary directed the OPTN to remove DSA as the initial distribution unit for lung allocation (21). The change, implemented November 24, 2017, distributes lungs first within a 250-nm radius from the donor hospital (21). A 250-nm radius was chosen rather than the 500-nm radius requested to mitigate the potential for unintended consequences of a sudden, large-scale change in organ distribution, particularly because prior modeling had predicted higher discard rates.

Impact

More time is required before the long-term impact of the policy change becomes apparent. Analysis of the first 12 months after implementation shows several trends. As expected, by increasing the pool of candidates in the initial distribution zone, mean LAS at time of transplant increased, from 47.25 in 2017 to 49.61 (22). But the offer number of the final acceptor is slightly higher. Taken together, these data raise the possibility that offers are being turned down by more high-LAS patients than previously, highlighting the difficult-to-address problem of variability in organ acceptance. There was no statistically significant change in overall waitlist mortality, although a small but statistically significant decrease was noted for recipients with an LAS between 60 and 70 (22).

Although there was a 58.7% decrease in allocation to a recipient within the donor DSA, most donor lungs continued to be distributed within a 250-nm region (22). However, mean travel distance per transplant has increased, with a small associated increase in ischemic time per organ (22). As predicted by Scientific Registry for Transplant Recipients modeling performed for the OPTN Thoracic Committee in 2009, an increase in donor lung discard rate was seen, from 4.86% to 6.42%. The reasons behind this increase remain unclear, and significant regional variations in discard rates persist (22). Single-center data remain limited. However, one large-volume center reported an increase in cost per transplant and a significant decrease in the number of local transplants (23).

Implications

Removing the DSA criteria was an important step toward reducing geographic disparity in donor lung distribution. Nonetheless, given that many DSAs, particularly in the western United States, are larger than a 250-nm circle, the transition had limited impact in terms of wider geographic distribution for the majority of recipients.

Although the shift toward greater geographic distribution rekindles concerns about potential decreased community engagement around organ donation, previous surveys suggest that potential organ donors reported valuing benefit from transplant over recipient location (24). More worrisome is the impact that loss of local donors may have on patients who require multiorgan transplant, including heart–lung and liver–lung candidates (25, 26). Because current allocation policy prioritizes multiorgan candidates only within the DSA, such patients are for the most part reliant on local donors for their eventual transplant (26, 27). Compared with lung transplant alone, these patients already have prolonged wait time and increased waitlist mortality.

The decrease in local allocation has increased concern about the potential for increased costs per organ procured. Although larger transplant programs may have the capacity to absorb these increased costs, for low-volume programs, the cost of travel to obtain organs may become prohibitive. This, combined with increasing travel and infrastructure costs associated with transplanting sicker patients, may increase the financial burden on smaller programs and add to their risk of closure (28).

Loss of smaller regional programs may have significant implications for rural patients and access to transplant and post-transplant care. Although existing data suggest that increased travel time is not associated with significant worsening of outcomes after transplant, the impact on patients who cannot travel to a larger transplant center remains to be determined (29).

Removal of the DSA has reduced geographic variability in organ allocation and is an important step toward transplant equity. The question remains: was the removal of DSA as a mechanism of reducing geographic discrimination effective as a mechanism of reducing waitlist mortality? In the short term, the answer appears to be no. A small but statistically significant increase in LAS has been reported; however, the clinical significance is unclear. We have reduced geographic restrictions to transplant. By no means have we solved the problem of waitlist mortality.

Next Steps

The successful transition from DSA-based modes of distribution highlights that for organ transplant, geography is not the limiting factor it once was. Where that limit now lies remains in question. Managing increased costs associated with expanding geographic barriers will likely become an increasingly pressing problem that challenges current procurement practices.

In addition, allocation policy change triggered by the lawsuit has forced the OPTN to address the underlying issues in an effort to preclude similar changes in the future. Most observers of this sudden change would agree that the more deliberate process typically used by the OPTN would be preferable. Given the conclusion by the OPTN Executive Committee that the use of DSA in allocation policy was not compliant with the Final Rule, work to remove DSA from all allocation policies is actively underway. However, geography is not the only consideration.

Following a lawsuit filed by a collective of patients in 2018, the OPTN removed DSA from the liver allocation policy, instead distributing organs through a series of expanding "acuity" circles 150 nm, 250 nm, and 500 nm from the donor hospital. The distribution starts by allocating to the most urgent patients and continues with less-urgent patients if no match is found within the final 500-nm circle (30, 31). This change was not universally endorsed and led to a second lawsuit, which argued that the changes relocated organs away from areas with high local donor rates, unfairly impacting patients in these regions (32, 33). The new system was implemented May 14, 2019, but returned to the original policy in response to a court order on May 23, 2019 (34). As of this writing, the original DSA system remains in place for liver transplant, awaiting a final court decision, and the OPTN is working to implement a "continuous

distribution" system, which will allow more seamless integration of the multiple factors important to equitable organ allocation and reduce the likelihood of future legal challenges to OPTN organ allocation policies.

To that end, the OPTN is working to develop a lung allocation policy incorporating distance as a continuous variable contributing to a composite score including medical urgency and equity variables. This approach is intended to mitigate the scenario where an organ is allocated to a candidate with a lower LAS ahead of a candidate with a higher LAS located slightly outside of a fixed circle boundary (35). How much weight to place on geographic proximity compared with other factors that predict successful transplant outcomes will need careful consideration, as will the potential impact of broadening geographic limits on ischemic time.

As long as there are fewer donor lungs available than recipients waiting, there will be limitations in our ability to distribute organs equitably. We must ensure that our system for distribution maximizes fairness and utility for transplant, while allowing cost-effective care. The changes to the lung allocation system reduce the potential for geographic discrimination, but do not meaningfully challenge the limits of geography. Work is ongoing to develop a system that can further optimize allocation, improving outcomes for those at highest risk of waitlist mortality. Of course, an important component of any solution to this problem is increasing the number of available donors and improving acceptance practices to make the best use of available donors. Efforts to reduce geographic variations in these domains are also underway. ■

Author disclosures are available with the text of this article at www.atsjournals.org.

Acknowledgment: The authors thank the members of the American Thoracic Society Health Policy Committee for input and feedback on this manuscript.

References

1 Valapour M, Lehr CJ, Skeans MA, Smith JM, Uccellini K, Lehman R, *et al*. OPTN/SRTR 2017 annual data report: lung. *Am J Transplant* 2019;19: 404–484.
2 Reiser SJ. Ethical aspects of organ allocation in transplantation. *Tex Heart Inst J* 1987;14:284–288.
3 Van Meter CH. The organ allocation controversy: how did we arrive here? *Ochsner J* 1999;1:6–11.
4 Egan TM. How should lungs be allocated for transplant? *Semin Respir Crit Care Med* 2018;39:126–137.
5 Colvin-Adams M, Valapour M, Hertz M, Heubner B, Paulson K, Dhungel V, *et al*. Lung and heart allocation in the United States. *Am J Transplant* 2012;12:3213–3234.
6 Institute of Medicine. Organ procurement and transplantation: assessing current policies and the potential impact of the DHHS final rule. Washington, DC: National Academy Press; 1999.
7 Merlo CA, Weiss ES, Orens JB, Borja MC, Diener-West M, Conte JV, *et al*. Impact of U.S. Lung Allocation Score on survival after lung transplantation. *J Heart Lung Transplant* 2009;28:769–775.
8 Egan TM, Edwards LB. Effect of the lung allocation score on lung transplantation in the United States. *J Heart Lung Transplant* 2016;35: 433–439.
9 Hachem RR, Trulock EP. The new lung allocation system and its impact on waitlist characteristics and post-transplant outcomes. *Semin Thorac Cardiovasc Surg* 2008;20:139–142.
10 Kozower BD, Meyers BF, Smith MA, De Oliveira NC, Cassivi SD, Guthrie TJ, *et al*. The impact of the lung allocation score on short-term transplantation outcomes: a multicenter study. *J Thorac Cardiovasc Surg* 2008;135:166–171.
11 Valapour M, Skeans MA, Smith JM, Edwards LB, Cherikh WS, Callahan ER, *et al*. Lung. *Am J Transplant* 2016;16:141–168.
12 Maxwell BG, Mooney JJ, Lee PHU, Levitt JE, Chhatwani L, Nicolls MR, *et al*. Increased resource use in lung transplant admissions in the lung allocation score era. *Am J Respir Crit Care Med* 2015;191: 302–308.
13 Flavin CM. Proposal to modify pediatric lung allocation policy. 2019 [accessed 2020 May 26]. Available from: https://optn.transplant.hrsa.gov/media/1279/policynotice_20140701.pdf.
14 Russo MJ, Worku B, Iribarne A, Hong KN, Yang JA, Vigneswaran W, *et al*. Does lung allocation score maximize survival benefit from lung transplantation? *J Thorac Cardiovasc Surg* 2011;141: 1270–1277.
15 Iribarne A, Meltzer DO, Chauhan D, Sonett JR, Gibbons RD, Vigneswaran W, *et al*. Distribution of donor lungs in the United States: a case for broader geographic sharing. *Clin Transplant* 2016;30:688–693.
16 Tsuang WM. Broader geographic sharing of donor lungs and the lung allocation score. *J Heart Lung Transplant* 2018;37:1141–1142.
17 Miriam Holman vs. United States Department of Health and Human Services. Verified complaint for a temporary restraining order and preliminary and permanent injunctive relief. Case 1:17-cv-09041. Document 1. Filed 11/19/17. 2017 Nov 19 [accessed 2019 Mar 31]. Available from: https://optn.transplant.hrsa.gov/media/2394/plaintiff_request_for_tro_20171119.pdf.
18 Holman vs. HHS, Case 1:17-cv-09041-LTS. Document 3-1 (Exhibit 1). Public Access to Court Electronic Records [filed 2017 Nov 20; accessed 201 Nov 20]. Available from: https://www.pacer.gov/.
19 Sigounas G. Department of Health and Human Services. Letter Re Court Order. 2017 Nov 21 [accessed 2019 Mar 31]. Available from: https://optn.transplant.hrsa.gov/media/2397/hrsa_letter_to_optn_20171121.pdf.
20 Glazier AK. The lung lawsuit: a case study in organ allocation policy and administrative law. *Journal of Health & Biomedical Law* 2018;XIV: 139–148.
21 Callahan LR, Ucellini K. Broader sharing of adult donor lungs. OPTN/UNOS Executive Committee; 2017 [accessed 2019 Mar 31]. Available from: https://optn.transplant.hrsa.gov/media/2314/broader_sharing_lungs_20171124.pdf.
22 Lehman RR, Carrico B. Monitoring of the lung allocation change, 9 month report removal of DSA as a unit of allocation. 2018 [accessed 2019 Mar 31]. Available from: https://optn.transplant.hrsa.gov/media/2730/20181025_thoracic_committee_report_lung.pdf.
23 Puri V, Hachem RR, Frye CC, Harrison MS, Semenkovich TR, Lynch JP, *et al*. Unintended consequences of changes to lung allocation policy. *Am J Transplant* 2019;19:2164–2167.
24 Health and Human Services, Health Resources and Services Administration. 2012 National Survey of Organ Donation Attitudes and Behaviors. 2013 [accessed 2019 Mar 31]. Available from: https://www.organdonor.gov/sites/default/files/about-dot/files/nationalsurveyorgandonation.pdf.
25 Iyengar A, Eisenring C, DePasquale E, Ross D, Ardehali A. Combined lung-liver transplantation: an analysis of the UNOS database. *J Heart Lung Transplant* 2016;35:S302–S303.
26 Freischlag KW, Messina J, Ezekian B, Mulvihill MS, Barbas A, Berg C, *et al*. Single-center long-term analysis of combined liver-lung transplant outcomes. *Transplant Direct* 2018;4:e349.
27 Wolf JH, Sulewski ME, Cassuto JR, Levine MH, Naji A, Olthoff KM, *et al*. Simultaneous thoracic and abdominal transplantation: can we justify two organs for one recipient? *Am J Transplant* 2013;13:1806–1816.
28 Mooney JJ, Weill D, Boyd JH, Nicolls MR, Bhattacharya J, Dhillon GS. Effect of transplant center volume on cost and readmissions in medicare lung transplant recipients. *Ann Am Thorac Soc* 2016;13: 1034–1041.
29 Tsuang WM, Lin S, Valapour M, Udeh BL, Budev M, Schold JD. The association between lung recipient travel distance and posttransplant survival. *Prog Transplant* 2018;28:231–235.

30 Kalra A, Biggins SW. New paradigms for organ allocation and distribution in liver transplantation. *Curr Opin Gastroenterol* 2018;34: 123–131.
31 Organ Procurement and Transplantation Network. OPTN/UNOS board approves updated liver distribution system. 2018 [accessed 2019 May 31]. Available from: https://optn.transplant.hrsa.gov/news/optnunos-board-approves-updated-liver-distribution-system/.
32 AP News. Hospitals sue over new national liver transplant policy. 2019 Apr 23 [accessed 2019 Aug 1]. Available from: https://www.apnews.com/59a564e232234ef9a4b9b9c6f4552f0f.
33 Dunn S, Shepard B. Health Resources and Services Administration memo to Organ Procurement and Transplantation Network. 2019 Mar 14 [accessed 2019 Aug 1]. Available from: https://optn.transplant.hrsa.gov/media/2914/hrsa-memo-to-optn-march-14-2019.pdf.
34 Organ Procurement and Transplantation Network. System notice: OPTN liver allocation policy reverted to DSA and regions. 2019 May 23 [accessed 2019 Aug 1]. Available from: https://optn.transplant.hrsa.gov/news/system-notice-optn-liver-allocation-policy-reverted-to-dsa-and-regions/.
35 Snyder JJ, Salkowski N, Wey A, Pyke J, Israni AK, Kasiske BL. Organ distribution without geographic boundaries: a possible framework for organ allocation. *Am J Transplant* 2018;18:2635–2640.
36 Washburn K. Maximizing donor potential: Evolving organ procurement organization metrics and optimizing organ distribution and allocation in the United States. *Liver Transpl* 2019;18(Suppl): S1–S4.