INTRODUCTION

The distribution of donor lungs in the United States is conditional on clinical measures of donor and recipient compatibility, geography, and, finally, priority based on calculated survival benefit from a transplant expressed by the Lung Allocation Score (LAS).\(^1,2\) The LAS is calculated by estimating candidates' likelihood of 1-year waitlist and 1-year posttransplant survival, giving risk of waitlist mortality twice the weight of posttransplant survival in its final computation. Currently, lung organ allocation first occurs for compatible candidates with the highest LAS within a 250–nautical mile radius and then follows farther circle cut-points if no suitable matches are identified within smaller concentric circles of allocation.\(^3\) Allocation decisions based on strict geographic boundaries resulted in arbitrary

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KEYWORDS

continuous distribution, geography, lung transplant, organ allocation, outcomes
cut-points and led to candidates with lower priority accessing organs ahead of higher priority candidates outside the geographic boundary. For example, in the current system, a candidate at 248 nautical miles with a lower LAS would preferentially receive access to an organ compared with a candidate at 252 nautical miles with a higher LAS. The Composite Allocation Score (CAS) system was developed to improve equity in organ allocation by eliminating hard geographic boundaries and considering geographic proximity in relation to other key factors in organ allocation, such as a transplant candidate’s medical priority.4

The Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) Lung Transplantation Committee was tasked with developing the CAS system to govern US lung allocation, making it the first organ system to undergo this change.3 This system would codify into one score all considerations in distribution of donor lungs, including the following components developed after lengthy deliberation and engagement with transplant stakeholders: medical urgency, posttransplant survival, candidate biology (blood type, human leukocyte antigen sensitization, candidate height), patient access (prior living donation, pediatric age group), and placement efficiency (travel and proximity). The new system was aligned with the goals of the OPTN Final Rule, which were to improve access to transplant, avoid futile transplants, efficiently place organs, and reduce the role of geography in allocation to the extent possible.4,5

The continuous distribution framework has a modular construct that allows for the adjustment of each component’s relative contribution to the final CAS to reflect a contemporary and collective ethos of the lung transplant community. To determine the weights of each component of the CAS, OPTN conducted multiple rounds of revealed preference analyses resulting in the assignment of 15% of the final score to “candidate biology” and 20% to “patient access.”6 However, the OPTN/UNOS lung committee of policymakers required further analysis to better understand the potential impact of different relative weights for “medical urgency,” “posttransplant survival,” and “placement efficiency” on lung transplant candidates, recipients, and transplant programs; this analysis is presented herein.

We quantified the possible effects of discrete allocation scenarios by designing multiple constructed models of the lung CAS system, altering the weight of medical urgency, posttransplant survival, and placement efficiency, and simulated their potential impact on waitlist mortality, posttransplant survival, and transplant programs. We hypothesized that the CAS may lead to improved system equity compared with current allocation parameters. These findings were presented to the OPTN/UNOS lung committee.

2 | METHODS

2.1 | Population

This study 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 United States, submitted by the members of the OPTN, and has been described elsewhere.7 Candidates on the lung transplant waiting list from January 1, 2018, through December 31, 2019, were included in the study cohort for simulations of pretransplant outcomes. This cohort was chosen to represent a contemporary cohort after the 2017 changes in lung allocation rules. For simulations of posttransplant outcomes, recipients who underwent transplant from January 1, 2018, through December 31, 2019, were included and administratively censored on March 12, 2020, due to changing transplant practice patterns with the emergence of COVID-19.

This research conforms to US Federal Policy for the Protection of Human Subjects. The study was conducted as secondary research on data collected on behalf of the US Federal Government, and as such is not considered human subjects research.

2.2 | Model structure

Six CAS allocation scenarios were developed and compared with current concentric circle–based allocation rules (Table 1). Three

<table>
<thead>
<tr>
<th>Component</th>
<th>1:1 WLAUC:PTAUC ratio</th>
<th>2:1 WLAUC:PTAUC ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10% PE</td>
<td>15% PE</td>
</tr>
<tr>
<td>Waitlist survival</td>
<td>25%</td>
<td>22.5%</td>
</tr>
<tr>
<td>Posttransplant survival</td>
<td>25%</td>
<td>22.5%</td>
</tr>
<tr>
<td>Candidate biology</td>
<td>15%</td>
<td>15%</td>
</tr>
<tr>
<td>Pediatric age</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>Prior living donor</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Placement efficiency</td>
<td>10%</td>
<td>15%</td>
</tr>
</tbody>
</table>

Note: Scenarios are grouped by the ratio (1:1 or 2:1) of WLAUC:PTAUC with varying PE weights of 10%, 15%, and 20%. The weight of each component, a total of 100%, differs by weighting percentages assigned to PE.

Abbreviations: PE, placement efficiency; PTAUC, posttransplant area under the curve; WLAUC, waitlist area under the curve.
sets of rules used a 1:1 ratio of the waitlist area under the curve (WLAUC) to posttransplant area under the curve (PTAUC), and the remaining three sets used a 2:1 ratio of the WLAUC:PTAUC. WLAUC is the expected number of days a candidate is expected to live during a year on the waiting list without transplant, and PTAUC is the expected number of days a recipient is expected to live during 5 years following transplant. A 5-year period was used to calculate PTAUC, which has been previously described. Placement efficiency, a composite of 50% proximity weight and 50% travel cost weight, carries weights varied at 10%, 15%, and 20% of the final score, with higher values placing greater weight on efficiency metrics. The WLAUC and PTAUC percentages differ (20%–25%) by the choice of placement efficiency weight and WLAUC:PTAUC ratio. Candidate biology includes a nonlinear curve for blood type (5%), calculated panel-reactive antibody (5%), and height (5%). Pediatric age priority is binary and comprises 20% of a candidate’s CAS. Prior living donor is binary and provides 5% for individuals who have donated a lung lobe for transplant. Posttransplant follow-up was limited to 2 years, because changes in allocation that occurred in 2017 did not permit a full 5-year period for study.

2.3 | Analysis

SRTR developed the thoracic simulated allocation model to simulate waitlist and posttransplant outcomes by allocation parameters. The model is a Monte Carlo simulation that uses historical donor, candidate, and offer data to model waitlist survival, organ offers, acceptance, and posttransplant survival and has been described elsewhere. Waitlist outcomes (waitlist mortality, deaths, transplant rates), transplant counts, and posttransplant outcomes (survival) were analyzed with the following subgroups: age, sex, race, ethnicity, height, blood type, LAS, WLAUC, PTAUC, diagnosis group (group A, obstructive lung disease; group B, pulmonary vascular disease; group C, cystic fibrosis and immunodeficiency disorders; and group D, restrictive lung diseases), OPTN region of transplant center, and center volume. Transplant counts, distribution, and posttransplant outcomes were analyzed by distance between donor and recipient for simulated transplants. Outcomes were also stratified by travel mode with expected to fly defined as donor-to-recipient distances greater than 75 nautical miles. Each simulation was repeated 10 times. The average, minimum, and maximum of each outcome were calculated by subgroup and overall. Further details about the models used in the simulation are provided in Table 1 and Appendix S1. Candidate LAS values were computed using the most recent LAS update from 2020, using a 1-year WLAUC and 1-year PTAUC that resulted from models fit on candidates and recipients from 2015 to 2018. Data presented by WLAUC use a 1-year WLAUC from a model fit on candidates from 2015 to 2018. Data presented by PTAUC use the 5-year PTAUC that resulted from a model fit on recipients from 2014 to 2018.

3 | RESULTS

The number of waitlist deaths declined considerably in all CAS scenarios compared with the current LAS system in which biological barriers to access are not given special consideration, geography has strict boundaries, and the ratio of 1-year WLAUC to 1-year PTAUC is 2:1. Under the simulation of the current system, 435 candidates died awaiting transplant, compared with 260, 269, and 280 deaths in the 1:1 CAS when placement efficiency was given weights of 10%, 15%, and 20%, and 231, 236, and 247 deaths in the 2:1 CAS when placement efficiency was given weights of 10%, 15%, and 20%, respectively. Declines in simulated waitlist deaths resulting from CAS scenarios ranged from 36% to 47%, with larger decreases in simulated deaths when placement efficiency was given the least weight and WLAUC was given a higher weight. Overall simulated transplant rates declined but were similar across CAS scenarios compared with under current allocation rules, likely due to longer waiting times for less urgent candidates. As expected, estimated transplant counts did not meaningfully differ, with 5056 transplants occurring under simulation of the current rules compared with a simulated 5064–5102 transplants over a 2-year period under the CAS system. Median distances between donor and recipient hospitals increased in all CAS scenarios when placement efficiency was given a lower weight, although this was not significantly affected by the ratio of WLAUC to PTAUC. Despite an increase in median distances traveled, the overall percentage of organs expected to fly declined with CAS (69.4%–79.0%) compared with under current rules (81.3%), reflecting likely trends of more local transplants but farther flying distances when organs are flown. Two-year predicted posttransplant survival was similar across scenarios for most subgroups (Table 1 and Figure 1).

3.1 | Allocation and LAS

We present results by LAS to ground the findings in a concept familiar to the lung transplant community with the acknowledgment that the LAS system will become extinct with the implementation of the CAS system. Simulated transplant rates paralleled LAS in a dose–response relationship with the lowest rates in the lowest LAS groups and with higher rates as LAS increased. Dramatic changes in projected transplants occurred for individuals with LAS values of 60 and greater, moving from 17% to 30%–32% under CAS scenarios. The greatest reduction in simulated waitlist deaths occurred for individuals with an LAS of 60 and greater, with further reductions in simulated deaths in scenarios with lower prioritization on efficiency (low placement efficiency) (Figure S1). Donor-to-recipient distances were greatest for this high LAS group.

3.2 | Allocation and WLAUC and PTAUC

Patterns by WLAUC mirrored patterns by LAS, with the greatest increase in transplant rate for the most severely ill quartile
of candidates (lowest WLAUC) and with the greatest increases occurring in scenarios with higher weighting of the WLAUC and lower weighting of placement efficiency (Figure 1). In the current allocation system, 75% of simulated waitlist deaths occurred in the lowest WLAUC quartile, and the greatest decline in simulated waitlist deaths occurred in this quartile in CAS scenarios. Notably, this quartile had the largest increases in simulated median donor-to-recipient distances under CAS scenarios. Transplant rates increased for candidates with the highest expected posttransplant survival (highest PTAUC quartile) while simulated rates decreased for those with the lowest expected posttransplant survival (lowest PTAUC quartile). Simulated waitlist deaths decreased in all PTAUC quartiles. Median donor-to-recipient distance increased in the two lowest PTAUC quartiles and decreased in the two highest quartiles with the highest placement efficiency weight (20%) (Figure S2).

3.3 | Allocation and age

Simulated transplant rates increased considerably for pediatric age (<18 years) candidates, increased moderately for candidates aged 18–49 years, and declined for candidates aged 65 years or older (Figure 2). The proportions of recipients younger than 50 years increased while those of recipients aged 65 years or older declined from 36% to 30%–33% in CAS scenarios. Despite decreased transplant rates in those aged 65 years or older, simulated waitlist deaths declined for all age groups. Median donor-to-recipient distances were highest for pediatric age candidates, reflecting the high priority given to pediatric age candidates in the CAS system (Figure S3). Among adults, higher distances occurred in scenarios with lower prioritization on efficiency (low placement efficiency). Organs allocated to pediatric age recipients had a high likelihood of being flown, whereas fewer organs were expected to be flown to candidates aged 50 years or older.

3.4 | Allocation and diagnosis

Pulmonary diagnoses are grouped for the LAS and upcoming CAS risk-adjustment models into the following categories: group A, obstructive lung disease; group B, pulmonary vascular disease; group C, cystic fibrosis and immunodeficiency disorders; and group D, restrictive lung diseases. Simulated transplant rates declined for diagnosis group B and D candidates and increased for group C candidates under the CAS scenarios; rates for group A candidates varied by scenario but largely declined. Waitlist deaths declined considerably for groups C (46 to 11–12) and D.
The proportion of transplants decreased for group A from 21.2% to 16.4%–20.5%, remained similar for groups B and D, and increased for group C from 8.6% to 10.1%–11.2%. Median distances increased for all CAS scenarios for groups B, C, and D, with decreased rates of flying for candidates in group A (Table 2).

### 3.5 Allocation and race, ethnicity, height, sex, and blood type

Simulated transplant rates increased for Latino candidates and decreased for White as well as Black candidates under most CAS scenarios compared with under current rules. Declines in waitlist deaths were more pronounced for Latino candidates. Transplant rates for shorter candidates, particularly those under 158 cm, increased compared with under current rules, even after removing children from the group. The number of waitlist deaths for shorter candidates declined by nearly half. Transplant rates declined for male candidates and were similar for female candidates under CAS scenarios compared with under current rules. Waitlist mortality decreased for both sexes, but the weight of placement efficiency affected female candidates more than male candidates. Transplant rates for candidates with blood type O increased considerably from 1.54 transplants per patient-year to 1.84–1.93 transplants per patient-year under CAS scenarios, and rates of all other blood types decreased compared with under current rules. Declines in waitlist deaths were more pronounced among type O candidates than other blood types. The proportion of recipients with type O blood increased from 45.6% to 51.1%–51.4%.

### 3.6 Allocation and distance, OPTN region, and center volume

The proportion of simulated transplants from donors less than 50 nautical miles and 250 nautical miles or greater increased in CAS scenarios. Proportions of transplants from distant donors were highest in scenarios with lower placement efficiency weights. Variability in transplant rates across regions was reduced from fourfold to twofold under CAS, and waitlist deaths declined across regions with no regions having increased waitlist deaths. Regional differences in median donor-to-recipient distances remained (see Figure 3). Transplant rates at the lowest-volume centers (<15 transplants/year) increased while rates at larger centers decreased compared with under current rules, a finding driven by increased transplant rates for pediatric age candidates (see Figure 4). Waitlist deaths declined for all centers regardless of volume of transplants performed (see Figure S5).
The main benefit of the CAS system over the current LAS system is that it is not governed by rigid boundaries between transplant candidates; rather, it uses a nuanced composite score that accounts for all candidate characteristics, with the goal of making access to lung transplants more equitable for patients in the United States. This analysis demonstrates that the CAS system reduced simulated waitlist mortality while providing similar simulated posttransplant survival. In some scenarios, there may be increased net societal survival gains by allowing more transplants to occur for individuals with greater predicted posttransplant survival—a previously elusive goal under the LAS system.

The CAS system also demonstrably reduced simulated geographic variability in candidates’ access to transplant while considering long-term survival. Taken together, these attributes of the CAS system make it the most sophisticated interpretation of the allocation priorities to date in accordance with the requirements of the Final Rule.3,12,13

### 4.1 Ethical framework

The key features of organ allocation are not clinical, rather they reflect salient societal values that mandate how the transplant community handles clinical realities. The governing ethical principles used to evaluate the CAS system are equity and utility—principles that have been codified by the National Organ Transplant Act (NOTA)14 and the OPTN Ethical Principles in Allocation of Human Organs15 and addressed by a recent consensus document from the International Society of Heart and Lung Transplantation.16

Development of the CAS provided an opportunity to be explicit about prioritization of ethical principles in the lung transplantation system,17 with components selected through a hybrid approach using multicriteria decision-making methodologies and an analytical hierarchy process to elicit feedback from lung transplant stakeholders to reflect societal values.6 To address equity, CAS incorporates candidate biology, a variable designed to measure candidate features that may limit access to transplant but have not been formally incorporated into the lung allocation system, including degree of sensitization, blood type, and height. In addition, pediatric age status remained an important distinctive criterion for allowing preferential access to transplant for this population—a preference supported by ethical principles such as the “fair innings principle.”15 The choice to provide special access to prior living donors of any organ also reflected a societal imperative to acknowledge living donors’ altruism. Medical urgency remained a prominent consideration to allow the sickest candidates timely access to transplant and was the primary driver for implementation of the CAS system. Considerations of long-term posttransplant survival and placement efficiency acknowledge that utility must be adequately considered in allocation of severely limited lifesaving resources.

### Table 2: Outcome counts and rates by Composite Allocation Score (CAS) scenario

<table>
<thead>
<tr>
<th>Outcome</th>
<th>1:1 WLAUC:PTAUC ratio</th>
<th>2:1 WLAUC:PTAUC ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transplant rate per patient-year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>1.77 (1.75-1.79)</td>
<td>1.64 (1.63-1.64)</td>
</tr>
<tr>
<td>Transplant count, No.</td>
<td>5056 (5038, 5068)</td>
<td>5081 (5064, 5095)</td>
</tr>
<tr>
<td>Waitlist mortality count, No.</td>
<td>23.4 (22.1, 24.4)</td>
<td>23.6 (22.2, 24.5)</td>
</tr>
<tr>
<td>Died (2-y posttransplant), %</td>
<td>23.4 (22.2, 24.4)</td>
<td>23.6 (22.2, 24.5)</td>
</tr>
<tr>
<td>Median donor-to-recipient distance, NM</td>
<td>491 (486, 496)</td>
<td>494 (489, 499)</td>
</tr>
<tr>
<td>Expected to fly (&gt;75 NM), %</td>
<td>81.3 (80.7, 82.3)</td>
<td>82.5 (81.9, 83.1)</td>
</tr>
</tbody>
</table>

Note: Current allocation rules were compared to six CAS scenarios that varied by weight of WLAUC:PTAUC and weight of PE. Measured outcomes include transplant rates (per patient-year), transplant count (over 2 years), waitlist mortality count (over 2 years), percentage who died (2 years posttransplant), median donor-to-recipient distance, and percentage expected to fly. All outcomes are reported as average (minimum, maximum) parts of the information contained in this table can be found in the SRTR report that can be found at this link: https://optn.transplant.hrsa.gov/media/4646/lu2021_01_cont_distn_report_final.pdf.

Abbreviations: NM, nautical mile; PE, placement efficiency; PTAUC, posttransplant area under the curve; WLAUC, waitlist area under the curve.
Trade-offs in choices

Three key elements of the continuous distribution framework were altered in the six presented scenarios: weight of WLAUC, weight of PTAUC, and placement efficiency. The remaining elements of candidate biology, pediatric age candidate, and prior living donor received stable weights of 15%, 20%, and 5%, respectively, in all scenarios. In models where WLAUC received increased weight (2:1 WLAUC:PTAUC), the risk of death on the waiting list is prioritized over posttransplant survival as is done in the current LAS system. Predictably, this strategy led to the lowest number of predicted waitlist deaths. On the other hand, when long-term PTAUC was given the same weight as WLAUC, the most simulated transplants occurred for individuals with the highest expected posttransplant survival. This comes at a cost of slightly higher waitlist mortality compared with the 2:1 scenario, but still led to a 40% decline in waitlist deaths compared with the current allocation system. Variation in placement efficiency weights mainly affected the median donor-to-recipient distance and percentage of organs expected to fly, with lower weights of placement efficiency resulting in higher median donor-to-recipient distances and an increased percentage of organs expected to fly. However, the lowest placement efficiency weights allowed for more transplants based on consideration of medical urgency (WLAUC) or utility (PTAUC). Under current rules, all adult candidates within 250 nautical miles have the same distance priority. Under CAS, donor lungs were often placed closer to the donor.
hospital, but, when they were not, they were placed much farther away (≥ 500 nautical miles), usually for a high-priority candidate.

4.3 | Efficiency in organ allocation

The Final Rule mandates efficiency in organ placement, with the meaning clarified by the Department of Health and Human Services to indicate that “broad geographic sharing should not come at the expense of wasting organs through excessive transportation times.” Efficiency was described by the concepts of increased volume/output, faster cycle times, or lower costs. Travel efficiency was considered to account for financial costs as an element of system efficiency leading to calculating of percentage of organs expected to fly. Ultimately a decision was made by the OPTN/UNOS Lung Transplantation Committee to use a general placement efficiency scale to serve as a proxy for non–cost-related efficiency (e.g., donor-to-transplant hospital distance). The committee opted not to include likelihood of acceptance, candidate and hospital density, “aura” placement whereby organ offers are grouped together and directed to a transplant program for candidates within a CAS range, or the ease of organ recovery. Placement efficiency was considered at weights of 10%, 15%, or 20% in this analysis. Note that the CAS system will likely be less efficient compared with the current allocation system due to higher costs associated with increasing the distance traveled to procure organs for high-priority candidates. This has already been observed with the change from donor service areas to 250 nautical miles as the first unit of allocation. Only after implementation of the CAS will we know the full impact of such a system on cost and efficiency. Adoption of the CAS system might result in innovations leading to more efficient organ procurement strategies or might place a strain on the procurement system if innovations or collaborations are not seriously pursued.

4.4 | Limitations

Simulations are simplifications of reality and, therefore, can only be validly compared with the other simulations. For this study, this means that the simulations may not predict what will happen in reality for future transplant waitlist cohorts once a new allocation system is adopted. Graphs and tables provide point estimates for the average of each metric, and error bars delineate the minimum and maximum of the range of the simulation. These can be misinterpreted as confidence intervals but demonstrate the average over 10 simulation runs, with the vertical bars showing the most...
extreme values obtained in the simulation. Because each simulation uses the same candidates and donors, samples are not independent; thus, $P$ values cannot be calculated. This analysis used an updated 5-year PTAUC model,\(^8\) which resulted in more differences between current rules and CAS rules than would be expected to occur with a 1-year PTAUC model, as is used in the current LAS. Only 2-year posttransplant survival is reported due to the lack of longer-term follow-up data; thus, 5-year survival outcomes might be underestimated.

5 | CONCLUSION

Across all simulated CAS scenarios, waitlist deaths decreased overall and for most subgroups compared with the current allocation algorithm. Waitlist deaths for those at greatest risk of death were minimized and transplants were maximized for those with the highest predicted posttransplant survival when the weight of placement efficiency was lowest. Giving waitlist and long-term survival equal weight in organ allocation (1:1 WLAUC:PTAUC) resulted in the highest percentage of transplants for candidates with the highest predicted posttransplant survival. These observations led to the OPTN/UNOS Lung Transplantation Committee’s decision to adopt a 1:1 WLAUC:PTAUC and 10% placement efficiency model to minimize waitlist deaths while maximizing gains in posttransplant survival. The CAS offers the lung transplant community a system able to adapt to changing preferences and needs as the landscape of lung transplantation evolves.

ACKNOWLEDGMENTS

This work was conducted under the auspices of the Hennepin Healthcare Research Institute (HHRI), contractor for the Scientific Registry of Transplant Recipients (SRTR), as a deliverable under contract no. 75R60220C00011 (US Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation). The US Government (and others acting on its behalf) retains a paid-up, nonexclusive, irrevocable, worldwide license for all works produced under the SRTR contract, and to reproduce them, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. The data reported here have been supplied by HHRI as the contractor for 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 of or interpretation by SRTR or the US Government. The authors thank SRTR colleague Anna Gillette for manuscript editing.

DISCLOSURE

The authors of this manuscript have no conflicts of interest to disclose as described by the American Journal of Transplantation. Parts of the manuscript contain information contained in the SRTR report that can be found at this link: https://optn.transplant.hrsa.gov/media/4646/lu2021_01_cont_distn_report_final.pdf.

DATA AVAILABILITY STATEMENT

Data are available upon request to the Scientific Registry of Transplant Recipients at https://www.srtr.org/requesting-srtr-data/data-requests/.

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REFERENCES


SUPPORTING INFORMATION
Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Valapour M, Lehr CJ, Wey A, Skeans MA, Miller J, Lease ED. Expected effect of the lung Composite Allocation Score system on US lung transplantation. Am J Transplant. 2022;22:2971-2980. doi:10.1111/ajt.17160