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Validating thoracic simulated allocation model predictions for impact of broader geographic sharing of donor lungs on transplant waitlist outcomes

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KEYWORDS:
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BACKGROUND: The thoracic simulated allocation model (TSAM) is used by the Scientific Registry of Transplant Recipients to predict the relative effect of organ allocation policy changes. A new lung allocation policy changing the first unit of allocation from donation service area to 250 nautical miles took effect on November 24, 2017. We studied TSAM's ability to correctly predict trends caused by changes in allocation policy.

METHODS: We compared the population characteristics from the TSAM cohort, 6,386 lung transplant candidates from 2009 to 2011, with the observed cohort of 7,601 candidates from the year before the policy change on November 24, 2017, and the year after. Simulations were run 10 times. Waitlist mortality and transplant rates were calculated and compared with observed mortality and transplant rates in the years before and after the policy change.

RESULTS: TSAM correctly predicted no change in overall waitlist mortality or transplant rates with the policy change. Observed waitlist mortality values were higher, as were transplant rates, because of increased organ donation and population change. TSAM predicted increased transplant rates for diagnosis group D (idiopathic pulmonary fibrosis), decreased rates for group A (chronic obstructive pulmonary disease), and increased rates for candidates with lung allocation score ≥50, but these changes did not occur in the waitlist and transplant populations after the policy change.

CONCLUSIONS: TSAM correctly predicted the relative trends caused by a change in allocation policy but smaller sub-group predictions were not seen.

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The United States organ transplant system aims to provide patients equitable and timely access to transplant. Over time, policies have developed to reduce subjectivity in organ allocation by emphasizing objective medical criteria and by minimizing the impact of waiting time and geography on access to transplant.[1] In lung transplantation, implementation of the lung allocation score (LAS) system addressed the goal of prioritizing allocation based on medical criteria rather than waiting time, but geography remained a major factor limiting access to transplant.[2,3] In response to a court order, on November 24, 2017, the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing Executive Committee enacted an emergency policy eliminating donation service area (DSA) as the first geographic unit of organ distribution in

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lung transplantation.[1,4,5] This policy change was justified because DSA boundaries were set based on historic precedent, were inconsistent in size, and did not correlate to organ viability.[6] The new temporary first geographic unit of distribution was a 250-nautical-mile (NM) circle surrounding the donor hospital until further studies could help refine this policy.[4]

To predict the possible effects of these changes in geographic donor organ distribution across the US, the Scientific Registry of Transplant Recipients (SRTR) used the thoracic simulated allocation model (TSAM), a discrete event-based, computer-based simulation program that uses historical data to model organ offers, acceptance, waitlist and post-transplant survival, and the uncertainty associated with these events. The TSAM has been used to study the potential impact of other proposed allocation changes, such as the changes to pediatric lung allocation implemented in 2017.[7] A number of investigators have recently published findings using the TSAM to reach conclusions about the best geographic distribution schemes to optimize outcomes for lung transplant candidates.[8,9] TSAM was designed to show the relative effect of new allocation rules on waitlist mortality and transplant rates in different waitlist sub-populations. Despite this reliance on the TSAM for research and policy decisions, its projections have never been compared with observed data occurring after a policy change. In this study, we present SRTR's TSAM predictions regarding the change from the previous DSA-first to the current 250-NM-circle lung allocation policy and compare predicted changes with observed changes that occurred from the year before the policy change (DSA population) to the year after implementation of the 250-NM-circle allocation policy (250-NM population).

Methods

We used the SRTR database, which includes data on all donors, candidates, and transplant recipients in the US, and has been described elsewhere.[10] Data are submitted by members of the OPTN with oversight provided by the Health Resources and Services Administration, US Department of Health and Human Services.[10]

Simulation design

SRTR developed the TSAM to simulate lung and heart allocation and waitlist and post-transplant outcomes. TSAM uses historical donor, candidate, and offer data to model waitlist survival, organ offers, acceptance, and post-transplant survival.[11] The simulation cohort included donors and candidates (including retransplant and multiorgan transplant candidates) from July 1, 2009, to June 30, 2011. Simulated offers were made to candidates based on different allocation rules, and offers were accepted or declined according to underlying statistical organ-acceptance models. Accepted offers were considered transplants, and simulated recipients were assigned predicted post-transplant death dates. Waitlist deaths occurred for candidates who either received no offers or accepted no offers. Each simulation was run 10 times (the standard number of software runs), and donors were randomly reordered to provide variability to the simulation studies.

TSAM is a Monte Carlo simulation, and the 10 simulation runs per set of allocation rules use the same candidates and donors. From TSAM simulation runs, we computed average waitlist mortality rates and transplant rates for DSA and 250-NM allocation rules. These are not independent samples, so traditional measures of variability or p-values cannot be computed in the comparison of outcomes across different sets of rules. TSAM is a tool for assessing access to transplant using different allocation rules and was not designed to precisely predict waitlist outcomes. Its value is in predicting trends in waitlist outcomes in one group relative to another.

Study populations

The TSAM population included lung transplant candidates and recipients aged ≥18 years from July 1, 2009, to June 30, 2011, the most recent subset of the population included in the TSAM. The observed population included lung transplant candidates and recipients aged ≥18 years from (1) November 24, 2016−November 23, 2017 (DSA population) and (2) December 1, 2017−November 30, 2018 (250-NM population). The analysis was limited to adults because they represent 99.7% of the lung transplant population, and the allocation schemes for adolescent (age 12−18 years) and child (age <12 years) candidates differ and already use broader geographic regions.[12]

Data analysis

Demographic and clinical characteristics of the TSAM population were compared with the combined observed DSA and 250-NM populations using chi-square tests. Lung transplant and waitlist mortality rates were compared between the simulation populations (for the DSA and 250-NM simulations) and in the 2 observed populations (DSA and 250-NM populations). These rates were plotted graphically to determine how well TSAM predicted both the direction and the magnitude of change between the allocation schemes. For rates resulting from the TSAM simulation, we plotted mean (95% confidence limits), minimum, and maximum per sub-group across the 10 simulation runs. We stratified rates by LAS, lung diagnosis group, and transplant center volume. Lung diagnosis was stratified as for the LAS calculation, by survival probability and pathophysiology of the underlying disease. Diagnosis groups include group A, obstructive lung disease; group B, pulmonary vascular disease; group C, cystic fibrosis and immunodeficiency disorders; and group D, restrictive lung disease.

Results

Study population

The TSAM population comprised candidates and recipients from July 1, 2009, to June 30, 2011; however, listing practices have changed in the last decade and the LAS was revised in 2015. The impact of these changes is clear when the TSAM candidate population is compared with the combined observed candidate populations. The more recent observed candidate population was older, with 30.9% of candidates aged ≥65 years, compared with 18.5% of candidates in the TSAM population ($p < 0.0001$). The observed population included more non-white candidates, 23.2% compared with 18.8% in the TSAM population ($p <$

0.0001). The observed population included more patients from diagnosis group D than the TSAM population, 55.6% and 43.5%, respectively ($p < 0.0001$), and included larger proportions of candidates with an LAS of ≥40, 38.5% compared with 30.2% (Table 1).

Similarly, the observed transplant recipient population included a greater proportion of older patients, with 33.0% of recipients aged ≥65 years, compared with 23.7% in the TSAM population ($p < 0.0001$), and more non-white recipients, 20.7% compared with 18.2% in the TSAM population ($p = 0.004$). The observed recipient population included more group D patients than the TSAM population, 58.8% and 53.3%, respectively ($p < 0.0001$), and a greater proportion of recipients with an LAS ≥60, 20.9% and 16.1%, respectively ($p < 0.0001$) (Table 2).

Tables 1 and 2 compare transplant candidates and recipients, respectively, in the TSAM (2009–2011) and observed populations (November 24, 2016–November 30, 2018) to highlight differences between the 2 populations. The observed DSA and 250-NM groups are combined in these tables because of similarity in most baseline patient characteristics and potential overlap of candidates and recipients. Supplementary Table S1, available online at www.jhtlonline.org, compares the TSAM population, DSA population, and 250-NM population and provides a 3-group comparison in addition to a pre- and post-policy population comparison.

Transplant and waitlist mortality rates

Overall predicted transplant rates were lower in the TSAM population than in the observed population. The TSAM predicted no meaningful change in transplant rates between allocation policies (137.5 transplants per 100 waitlist-years, TSAM DSA; 137.0, TSAM 250-NM) (Figure 1). Similar to the prediction, we found no change in transplant rates in the observed populations (206.9 transplants per 100 waitlist-years, observed DSA; 202.5, 250-NM). Although TSAM-predicted transplant rates differed from observed rates, the predicted trend of no meaningful change held true. Differences in magnitude were expected, as (1) the lung donor population increased 41% from 2011 to 2018 (data from the 2019 OPTN/SRTR Annual Date Report, to be published in early 2020), and (2) the proportion of high-urgency candidates increased between the 2 periods.

Overall TSAM-predicted waitlist mortality rates were lower than in the observed populations. The TSAM predicted 13.6 deaths per 100 waitlist-years in the DSA simulation and 12.8 in the 250-NM simulation. This comparison was similar in the observed populations, with 15.8 deaths per 100 waitlist-years in the DSA population and 16.7 in the 250-NM population. The confidence limits overlapped, suggesting no difference in overall waitlist morality rates. Waitlist mortality rates were higher in the observed population than in TSAM predictions, although rates did not differ meaningfully between DSA and 250-NM allocation rules in either the predicted or the observed population. This increase may be due to (1) a sicker population awaiting transplant in a more current era and (2) structural elements

Table 1 Characteristics of the TSAM (2009–2011) and Observed Waitlist Cohorts (November 24, 2016–November 23, 2017; December 1, 2017–November 30, 2018)

Characteristics	TSAM *n* (%)	Observed *n* (%)	*p*-value
Age, years			
18–34	866 (13.56)	722 9.50	<0.0001
35–49	1,149 (17.99)	984 (12.95)	
50–64	3,191 (49.97)	3,544 (46.63)	
≥65	1,180 (18.48)	2,351 (30.93)	
Sex			
Male	3,206 (50.20)	4,065 (53.48)	0.0001
Female	3,180 (49.80)	3,536 (46.52)	
Race/ethnicity			
White	5,185 (81.19)	5,837 (76.79)	<0.0001
Black	635 (9.94)	806 (10.60)	
Hispanic	397 (6.22)	678 (8.92)	
Asian	124 (1.94)	227 (2.99)	
Other/unknown	45 (0.70)	53 (0.70)	
Diagnosis group[a]			
A	2,324 (36.39)	2,171 (28.56)	<0.0001
B	537 (8.41)	513 (6.75)	
C	748 (11.71)	689 (9.06)	
D	2,777 (43.49)	4,228 (55.62)	
Blood type			
A	2,491 (39.01)	2,821 (37.11)	0.089
B	709 (11.10)	857 (11.27)	
AB	200 (3.13)	271 (3.57)	
O	2,986 (46.76)	3,652 (48.05)	
OPTN region			
1	259 (4.06)	277 (3.64)	<0.0001
2	915 (14.33)	1,346 (17.71)	
3	770 (12.06)	759 (9.99)	
4	757 (11.85)	812 (10.68)	
5	841 (13.17)	1,219 (16.04)	
6	170 (2.66)	196 (2.58)	
7	545 (8.53)	610 (8.03)	
8	440 (6.89)	441 (5.80)	
9	254 (3.98)	391 (5.14)	
10	824 (12.90)	980 (12.89)	
11	611 (9.57)	570 (7.50)	
Initial LAS			
<35	2,969 (46.49)	2,569 (33.80)	<0.0001
35–<40	1,489 (23.32)	2,106 (27.71)	
40–<50	1,069 (16.74)	1,548 (20.37)	
50–<60	319 (5.00)	477 (6.28)	
≥60	540 (8.46)	901 (11.85)	
Annual program volume[b]			
<10	256 (4.01)	152 (2.00)	<0.0001
10–25	1,747 (27.36)	1,321 (17.38)	
>25–50	2,011 (31.49)	2,488 (32.73)	
>50–75	1,021 (15.99)	1,062 (13.97)	
>75	1,351 (21.16)	2,578 (33.92)	
All	6,386 (100.00)	7,601 (100.00)	

Abbreviations: LAS, lung allocation score; OPTN, Organ Procurement and Transplantation Network; TSAM, thoracic simulated allocation model.

[a]Diagnosis group A: chronic obstructive pulmonary disease; diagnosis group B: idiopathic pulmonary hypertension; diagnosis group C: cystic fibrosis; diagnosis group D: idiopathic pulmonary fibrosis.

[b]Transplants per year.

Table 2 Characteristics of the TSAM (2009–2011) and Observed Transplant Cohorts (November 24, 2016–November 23, 2017; December 1, 2017–November 30, 2018)

Characteristics	TSAM *n* (%)	Observed *n* (%)	*p*-value
Age, years			
18–34	418 (12.63)	493 (9.99)	<0.0001
35–49	489 (14.77)	581 (11.77)	
50–64	1,619 (48.91)	2,234 (45.25)	
≥65	784 (23.69)	1,629 (33.00)	
Sex			
Male	1,873 (56.59)	2,937 (59.49)	0.009
Female	1,437 (43.41)	2,000 (40.51)	
Race/ethnicity			
White	2,709 (81.84)	3,916 (79.32)	0.004
Black	317 (9.58)	480 (9.72)	
Hispanic	201 (6.07)	389 (7.88)	
Asian	60 (1.81)	124 (2.51)	
Other/unknown	23 (0.69)	28 (0.57)	
Diagnosis group[a]			
A	956 (28.88)	1,274 (25.81)	<0.0001
B	187 (5.65)	264 (5.35)	
C	403 (12.18)	494 (10.01)	
D	1,764 (53.29)	2,905 (58.84)	
Blood type			
A	1,300 (39.27)	1,934 (39.17)	0.035
B	400 (12.08)	555 (11.24)	
AB	93 (2.81)	195 (3.95)	
O	1,517 (45.83)	2,253 (45.64)	
OPTN region			
1	96 (2.90)	198 (4.01)	<0.0001
2	489 (14.77)	824 (16.69)	
3	396 (11.96)	497 (10.07)	
4	412 (12.45)	584 (11.83)	
5	450 (13.60)	779 (15.78)	
6	81 (2.45)	100 (2.03)	
7	273 (8.25)	367 (7.43)	
8	220 (6.65)	292 (5.91)	
9	120 (3.63)	210 (4.25)	
10	403 (12.18)	631 (12.78)	
11	370 (11.18)	455 (9.22)	
Initial LAS			
<35	745 (22.51)	1,172 (23.74)	<0.0001
35–<40	762 (23.02)	1,103 (22.34)	
40–<50	871 (26.31)	1,176 (23.82)	
50–<60	398 (12.02)	453 (9.18)	
≥60	534 (16.13)	1,033 (20.92)	
Annual program volume[b]			
<10	109 (3.29)	79 (1.60)	<0.0001
10–25	870 (26.28)	785 (15.90)	
>25–50	977 (29.52)	1,571 (31.82)	
>50–75	523 (15.80)	758 (15.35)	
>75	831 (25.11)	1,744 (35.33)	
All	3,310 (100.00)	4,937 (100.00)	

Abbreviations: LAS, lung allocation score; OPTN, Organ Procurement and Transplantation Network; TSAM, thoracic simulated allocation model.

[a]Diagnosis group A: chronic obstructive pulmonary disease; diagnosis group B: idiopathic pulmonary hypertension; diagnosis group C: cystic fibrosis; diagnosis group D: idiopathic pulmonary fibrosis.

[b]Transplants per year.

in the TSAM that typically predict lower than observed waitlist mortality rates, which occurs because individuals who receive a simulated offer before their (actual) death count as a transplant rather than a waitlist death.

Transplant and waitlist mortality by primary diagnosis

Transplant rates varied by primary diagnosis. The TSAM predicted slightly increased transplant rates for group D and slightly decreased rates for group A, with 250-NM compared with DSA as the first unit of allocation (Figure 1). These small changes did not occur in observed data. Predicted transplant rates in groups B and C were similar in DSA and 250-NM simulations but populations were small, resulting in large 95% confidence limits. In simulated and observed data, under both policies, transplant rates were highest for diagnosis group D. For each diagnosis group, predicted and observed waitlist mortality were similar under DSA and 250-NM policy.

Transplant and waitlist mortality by LAS

Transplant rates and waitlist mortality by LAS varied across LAS category (LAS <30, 30–<35, 35–<40, 40–<50, 50–<60, and ≥60) (Figure 2). Generally, transplant rates were higher for high-LAS and lower for low-LAS groups. As in the overall data, TSAM-predicted transplant rates were lower than observed rates in general. Increases in transplant rates did not occur in the observed data, although the pattern of increased transplant rates at higher LAS occurred in simulated and observed data. For LAS ≥60, predicted transplant rates were 15% higher in the 250-NM simulation than in the DSA simulation. Observed rates were 11% higher in the 250-NM simulation, although 95% confidence limits overlapped and the difference was not statistically significant. Within LAS groups, predicted waitlist mortality did not differ by allocation rules.

Transplant and waitlist mortality by transplant program volume

Observed transplant rates and waitlist mortality were on average higher than TSAM predictions for programs that perform ≥10 transplants per year (Figure 3). For programs performing <10 transplants per year, observed transplant rates decreased with the change from DSA to 250-NM allocation rules, although the TSAM had predicted no change. TSAM predicted an increase in transplant rates for programs performing >75 transplants per year. There was no significant difference in observed rates, but in both simulated and observed data, transplant rates were higher at larger programs. Waitlist mortality did not change significantly in the DSA compared with the 250-NM population by program volume in the observed data.

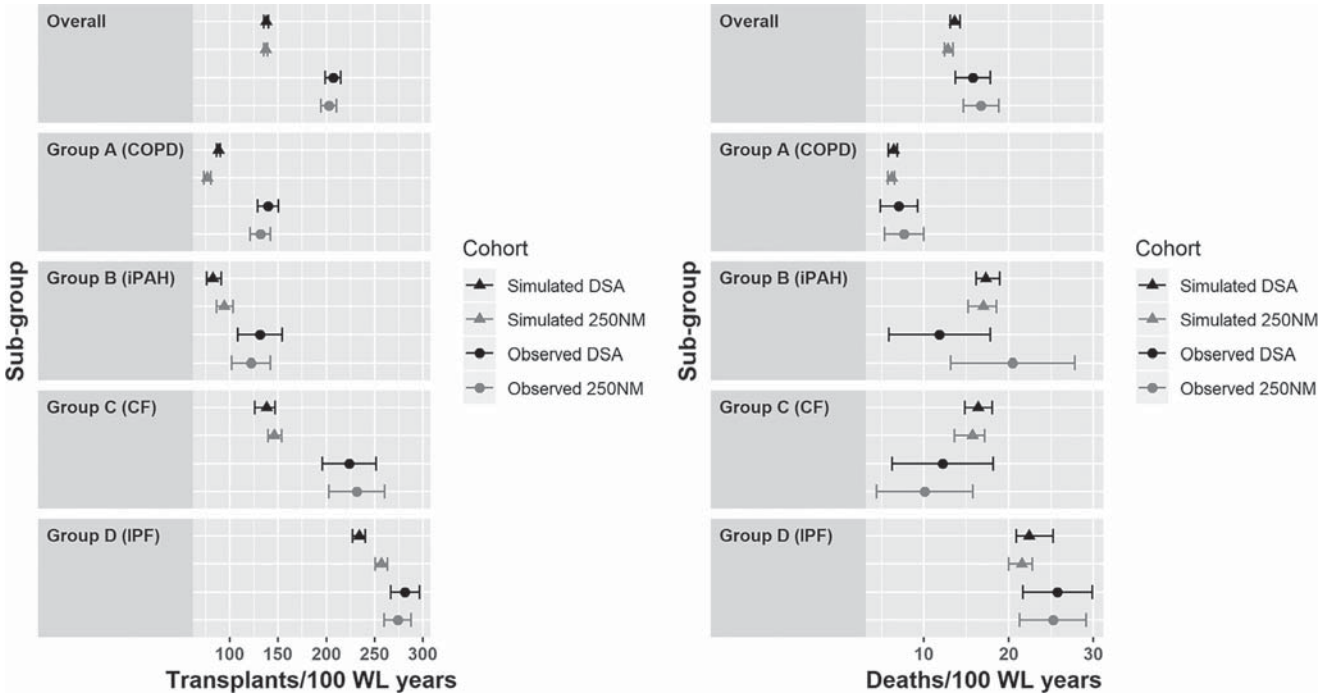

Figure 1 Transplant and waitlist mortality rates by primary diagnosis group. Predicted transplant rates and waitlist mortality (TSAM) in the simulated DSA-first allocation scheme (black triangle) compared with the simulated 250-NM simulation (gray triangle) by primary diagnosis group. Observed transplant rates and waitlist mortality in the DSA-first lung allocation policy (black circle) compared with the 250-NM allocation policy (gray circle). Simulated rates are shown as mean, minimum, and maximum rates per sub-group across 10 simulation runs. Observed rates are shown as means and 95% confidence limits. CF, cystic fibrosis; COPD, chronic obstructive pulmonary disease; DSA, donation service area; IPAH, idiopathic pulmonary arterial hypertension; IPF, idiopathic pulmonary fibrosis; NM, nautical mile; TSAM, thoracic simulated allocation model; WL, waitlist.

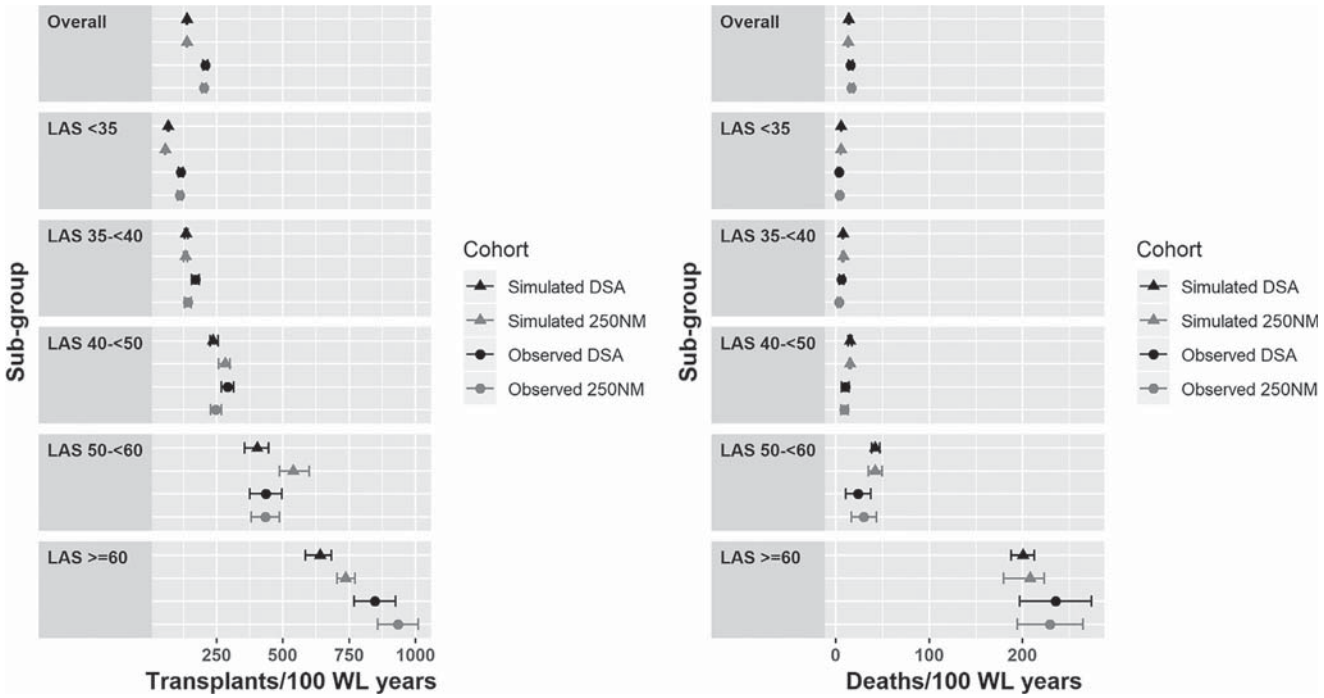

Figure 2 Transplant and waitlist mortality rates by LAS. Predicted transplant rates and waitlist mortality compared with observed values stratified by LAS. Transplant rates increased with increasing LAS but did not differ meaningfully by changes in geographic distribution area. Simulated rates were generally lower than observed rates. Waitlist mortality increased with LAS without a meaningful difference by changes in geographic distribution area. DSA, donation service area; LAS, lung allocation score; NM, nautical mile; WL, waitlist.

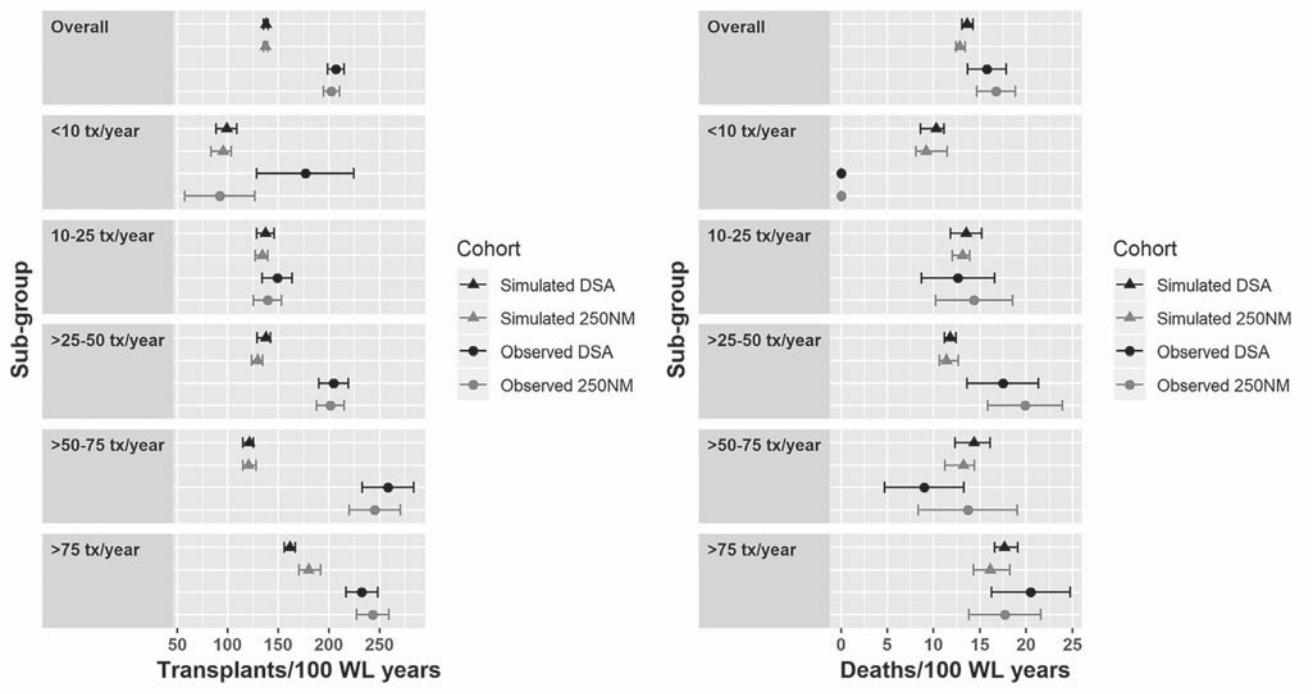

Figure 3 Transplant and waitlist mortality rates by program transplant volume. Predicted transplant rates and waitlist mortality compared with observed values by geographic distribution area stratified by transplant center volume. Transplant rates generally increased with increasing center volume and observed rates were higher than TSAM predictions. The number of transplants occurring at low volume centers (<10 transplants per year) decreased with the change from DSA to 250-NM allocation policy. DSA, donation service area; NM, nautical mile; TSAM, thoracic simulated allocation model; tx, transplant; WL, waitlist.

Discussion

Major findings

We found that the TSAM was a reliable predictor of the impact of broader geographic sharing of donor lungs following replacement of DSA by 250-NM as the first unit of allocation in US lung transplantation. TSAM predicted no overall change in transplant rates or waitlist mortality, and few changes have been observed so far, demonstrating that the structure of the simulation model reliably predicted the relative impact of the geographic allocation change. Actual observed transplant rates and waitlist mortality were higher than the TSAM predicted, which was expected given the increase in the donor population and the increase in the proportion of high-LAS candidates since the TSAM population ended in 2011. Important updates to the LAS, changes in the waitlist and transplant populations, and an increase in deceased donors have occurred since that time.[12] Because of the mandate from the emergency injunction in November 2017, SRTR could not perform the time-intensive update to the TSAM population before developing models to predict the effect of the change from DSA to 250-NM as the first unit of lung allocation.

TSAM performance in predictions for subgroups

TSAM predicted that a change from DSA to 250-NM allocation rules would result in an increase in transplant rates for group D, the group with the highest simulated rate, and a decrease for group A, the group with the lowest simulated rate. These predictions were not realized in the observed population, although group D did maintain the highest rates and group A the lowest transplant rates. This rate mismatch may be affected by the LAS score revision that was implemented on February 19, 2015. After the LAS revision, waiting times became shorter, the number of group D candidates stabilized, and the prevalence of extremely high LAS values decreased.[13] Although TSAM predicted increased transplant rates under the 250-NM allocation rules for patients with an LAS ≥50, observed rates were similar between the 2 allocation rules. A concern related to the DSA-based system was that organs were being allocated to lower-priority recipients; however, the comparison of a year of pre-policy and a year of post-policy transplants did not show an increase in transplant rates for candidates in the higher LAS categories.[14,15] In candidates with an LAS of ≥60, TSAM underestimated the magnitude of transplant rates and overestimated the difference in the observed data with the policy change.

TSAM did not predict a difference in transplant rates for programs of similar volume; however, transplant rates decreased at programs performing <10 transplants per year. Only 152 candidates (2.0% of the total) were listed at programs performing <10 transplants per year in the observed population, compared with 256 candidates (4.0%) in the TSAM population. The small number of candidates undergoing transplant at such programs may limit the strength of this finding.

Differences between TSAM predictions and actual observations

The TSAM predictions underestimated both waitlist mortality and transplant rates. These changes may be due to increased transplant rates, increased donor numbers, and the 2015 LAS revision, none of which are represented in the TSAM population from 2009 to 2011.[12] The number of lung transplants has increased yearly, from 1,849 at the end of the TSAM population to 2,478 in 2017, an increase of 34%.[12] The number of transplants has grown because of increasing use of technology, such as ex vivo lung perfusion, and the increased number of donors as a result of the opioid epidemic, an increase of 350% from 2003 to 2014.[16,17]

Transplant rates have increased yearly since the end of the TSAM population. From 2009 to 2011, transplant rates ranged from 87.1 to 102.8 transplants per 100 waitlist-years, and in 2017, transplant rates among adult candidates increased to 173.2 transplants per 100 waitlist-years. Waitlist mortality remained more stable over this period, ranging from 15.1 to 17.9 deaths per 100 waitlist-years despite an increase in illness severity in lung transplant candidates. Over the past 5 years, more candidates now require intensive care unit hospitalization, mechanical ventilation, and extracorporeal membrane oxygenation support before transplant. The median LAS has not changed considerably since 2011, but this may be due to changes in LAS score calculation after the 2015 revision. Although the populations in TSAM and observed data differed, the predicted trend was often similar to the observed data, highlighting the value of TSAM, despite limitations of an older population, for studying potential changes to organ allocation.[12]

How TSAM compares to other simulated allocation models

Simulated allocation models have been used in thoracic (TSAM), liver (liver simulated allocation model [LSAM]), and kidney and pancreas allocation to study the potential impact of allocation changes.[18] The LSAM was validated by comparing projections before and after the Share 35 policy (2013), producing similar candidate, recipient, and donor characteristics, and it correctly predicted the directionality of changes in transplant rates.[19] The LSAM underestimated the number of transplants and overestimated waitlist deaths as a result of the Share 35 policy, whereas the TSAM underestimated both transplant rates and waitlist mortality as a result of the change from DSA to 250-NM as the first unit of allocation in lung transplantation. The kidney and pancreas simulated allocation model has been used to study the impact of the kidney donor profile index, leading to the implementation of a new kidney allocation system in 2014, and was used to model waitlist time in the pre− and post−kidney allocation system eras.[20,21]

Limitations

Limitations of simulated allocation models include simplification of the complex system of organ allocation, inability to account for changes in listing or acceptance practices, and lack of granular data to estimate program-specific effects of allocation changes. The TSAM is limited by the use of retrospective populations and simulation of effects of allocation 1 year at a time, which prevents the study of long-term effects of a policy change in a modern population. Simulation models do not use program-level data and they cannot generate more granular predictions for 2 reasons. First, small numbers, as is the case in program-level transplant data, would generate unpredictable estimates; second, all models, including organ acceptance models, are based on national experience and do not account for variation in program-level practices. An additional limitation is that mortality models are based on overall data and TSAM predicts outcomes less well for small groups. Finally, TSAM cannot account for changes in listing or acceptance behavior caused by changes in policy, nor can it account for changes in the donor pool or the addition of new technology such as ex vivo lung perfusion or increasing use of extracorporeal membrane oxygenation.

In this work, we tested the ability of the TSAM to predict changes in transplant rates and waitlist mortality in an out-of-sample population. We found that the TSAM correctly predicted that the change from DSA to 250-NM allocation rules would not meaningfully affect transplant or waitlist mortality rates but was unable to predict the magnitude of these rates. Predicted transplant and waitlist mortality rates differed in magnitude between the TSAM and the observed population, reflecting the TSAM's use of a population that is outdated by nearly a decade and an increasing number of donors over time. Although TSAM predicted trends correctly, interpretation of results should focus on relative change, rather than anchor to specific predicted rates. Decision makers should be aware of this limitation and use results accordingly when cohorts are not current. The TSAM should be updated to ensure that a current cohort is used to simulate important future changes in geographic allocation rules.

Disclosure statement

The authors have no conflicts of interest to disclose.

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Supplementary data

Supplementary data associated with this article can be found in the online version at www.jhltonline.org.

Supplementary materials

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References

1. Health and human services. The final rule. Available at: https://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211-cac77d1&mc=true&node=pt42.1.121&rgn=div5.
2. 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.
3. Egan TM, Edwards LB. Effect of the lung allocation score on lung transplantation in the United States. J Heart Lung Transplant 2016;35:433-9.
4. United Network for Organ Sharing. Policy modification to lung distribution sequence. Available at: https://optn.transplant.hrsa.gov/news/policy-modification-to-lung-distribution-sequence/.
5. Glazier AK. The lung lawsuit: A case study in organ allocation policy and administrative law. J Heal Biomed L 2018;14:139-48.
6. Holman vs United. States Department of Health and Human Services (Case 1:17-cv-09041). Available at: https://optn.transplant.hrsa.gov/media/2394/plaintiff_request_for_tro_20171119.pdf.
7. 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.
8. Mooney JJ, Bhattacharya J, Dhillon GS. Effect of broader geographic sharing of donor lungs on lung transplant waitlist outcomes. J Heart Lung Transplant 2019;38:136-44.
9. Egan TM. On broader geographic sharing of donor lungs. J Heart Lung Transplant 2019;38:127-9.
10. Leppke S, Leighton T, Zaun D, et al. Scientific Registry of Transplant Recipients: collecting, analyzing, and reporting data on transplantation in the United States. Transplant Rev (Orlando) 2013;27:50-6.
11. Scientific Registry of Transplant Recipients. Thoracic simulated allocation model user guide. Available at: https://www.srtr.org/media/1201/tsam.pdf.
12. Valapour M, Lehr CJ, Skeans MA, et al. OPTN/SRTR 2017 annual data report: lung. Am J Transplant 2019;19(Suppl 2):404-84.
13. Valapour M, Lehr CJ, Skeans MA, et al. OPTN/SRTR 2016 annual data report: lung. Am J Transplant 2018;18(Suppl 1):363-433.
14. 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. discussion 1234-5.
15. Iribarne A, Meltzer DO, Chauhan D, et al. Distribution of donor lungs in the United States: a case for broader geographic sharing. Clin Transpl 2016;30:688-93.
16. Van Raemdonck D, Neyrinck A, Cypel M, Keshavjee S. Ex−vivo lung perfusion. Transpl Int 2015;28:643-56.
17. Goldberg DS, Blumberg E, McCauley M, Abt P, Levine M. Improving organ utilization to help overcome the tragedies of the opioid epidemic. Am J Transplant 2016;16:2836-41.
18. SRTR. Simulated allocation models. Available at: https://www.srtr.org/requesting-srtr-data/simulated-allocation-models/.
19. Goel A, Kim WR, Pyke J, et al. Liver simulated allocation modeling: were the predictions accurate for share 35? Transplantation 2018;102:769-74.
20. Torlak F, Ayvaci MU, Ahsen ME, Arce C, Vazquez MA, Tanriover B. Estimating waiting time for deceased donor renal transplantation in the era of new kidney allocation system. Transplant Proc 2016;48:1916-9.
21. Israni AK, Salkowski N, Gustafson S, et al. New national allocation policy for deceased donor kidneys in the United States and possible effect on patient outcomes. J Am Soc Nephrol 2014;25:1842-8.