Published in final edited form as:

Am J Transplant. 2019 August ; 19(8): 2164–2167. doi:10.1111/ajt.15307.

Unintended Consequences of Changes to Lung Allocation Policy

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Abstract

Organ allocation for transplantation aims to balance the principles of justice and medical utility to optimally utilize a scarce resource. To address practical considerations, the U.S. is divided into 58 donor service areas (DSA), each constituting the first unit of allocation. In November 2017, in response to a lawsuit in New York, an emergency action change to lung allocation policy replaced the DSA level of allocation for donor lungs with a 250 nautical mile circle around the donor hospital. Similar policy changes are being implemented for other organs including heart and liver.

Findings from a recent U.S. Department of Health and Human Services report, supplemented by data from our institution, suggest that the emergency policy has not resulted in a change in the type of patients undergoing lung transplantation (LT) or early postoperative outcomes. However, there has been a significant decline in local LT, where donor and recipient are in the same DSA. With procurement teams having to travel greater distances, organ ischemic time has increased and median organ cost has more than doubled. We propose potential solutions for consideration at this critical juncture in the field of transplantation. Policymakers should choose equitable and sustainable access for this lifesaving discipline.

Organ allocation for transplantation in the U.S. aims to balance the principles of justice and medical utility to optimize utilization of a scarce resource. To address practical considerations, the country is divided into 58 donor service areas (DSA) that have conventionally been the first unit of allocation[1]. On November 24, 2017, in response to a lawsuit in New York, an emergency action change to lung allocation policy removed the

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Disclosure

The authors of this manuscript have no conflicts of interest to disclose as described by the *American Journal of Transplantation*.

Data Availability Statement

Deidentified data from the BJH patient population discussed in the paper will be made available upon request with appropriate institutional review board approval and data use agreements.

DSA level of allocation for donor lungs and replaced it with a 250 nautical mile circle around the donor hospital[2]. Similar policy change for other organs including heart and liver have been or are currently being implemented.

The Organ Procurement and Transplantation Network (OPTN) of the U.S. Department of Health and Human Services brings together medical professionals, transplant recipients, and donor families to develop organ transplantation policy. Recently, the OPTN published a 6-month report describing nationwide Lung Transplantation (LT) data since the implementation of the new allocation policy[3]. The findings of this report were congruent with the 4-month data analysis from the OPTN. With 1142 deceased donor LTs in the immediate 6-month pre-policy era and 1146 in the 6-month post–policy era, there was no significant change in the LT volume. The number of donation after cardiac death (DCD) transplants increased from 39 to 61, reflecting a general trend of increasing use of DCD lung donors[3]. As expected, there was a small increase in the mean lung allocation score (LAS) of transplanted patients (47.85 vs. 49.96, p=0.005), where a higher LAS represents clinically sicker patients. This difference in LAS, though statistically significant, is small and likely represents patients with a similar disease process (usually interstitial lung disease), and disease severity,

The OPTN report also highlighted some concerning findings. With a greater likelihood of longer travel distances for lung procurement under the new policy, the mean ischemic time (time between organ procurement and implantation) increased from 5.33 hours to 5.53 hours (p=0.016), though this may not be clinically meaningful. Additionally, there was a 56% decline in local LT, defined as the donor and recipient belonging to the same DSA, which traditionally facilitates coordination between multiple organ transplant teams, minimizes travel times, and lowers organ procurement costs. For a variety of physiologic reasons, national lung utilization rates (LUR, proportion of potential donors who are utilized for LT) are significantly lower than those for livers and kidneys, thus making lungs a particularly precious resource. With implementation of the policy change, 8 of 11 national regions saw a decline in their LUR, however, the absolute LUR remained stable around 22%, with 2 regions exhibiting a significant increase in LUR. Notably, the discard rate, which refers to lungs procured but not transplanted, increased from 4.74% to 6.13%. Again, 8 of 11 national regions noted an increase in the discard rate. However, as the overall discard rate remains low, the potential impact of this recent increase in discard rate remains to be evaluated. Finally, the use of ex-vivo lung perfusion (EVLP), an expensive technique that is utilized to assess lungs with marginal quality, increased substantially after the policy change (42 pre vs. 119 post), particularly in the 2 OPTN regions with higher LUR after policy change. With the OPTN report not providing any information on outcomes or cost in the two eras, we aim to present additional data that may inform policy in the field.

With over 1650 transplants to date, Barnes Jewish Hospital (BJH) is the site of a well-established, high volume LT program that supports clinical and laboratory research[4]. Since the 14 busiest LT programs perform nearly 35 % of LT in the U.S., many aspects of the practice patterns and outcomes at BJH are reflective of national practice[5]. We abstracted clinical data from a prospectively maintained LT database at BJH and collaborated with Mid-America Transplant (MTS), the local organ procurement organization (OPO) in our

DSA, to understand the financial consequences of the new policy. In 2001, MTS established a specialized donor care facility, with the goal of simplifying donor care and optimizing organ yield. This unique model has led to organ recovery rates comparable to or better than conventional, hospital-based donor management while also leading to cost savings for the system[6,7]. Since then, at least 12 other OPOs have adopted or are in the process of adopting this model of care. For the current study, a convenience sample was chosen to compare LT pre-policy (1.1.17 to 11.23.17) versus post-policy (11.25.17 to 6.4.18). The sample analyzed included all lung transplants performed at our institution in the calendar year 2017 prior to policy change and all transplants performed after policy change till data were abstracted for the current study.

A summary of these data is shown in Table 1. The donors were of similar age and organ quality, however there was a nearly 50% decline in local LT. The recipients in the two eras were comparable in diagnoses, disease severity (LAS), need for preoperative mechanical ventilation, and time spent on the waitlist. The short-term outcomes including graft dysfunction, operative mortality, and length of stay were similar in the two groups. As expected, with fewer local transplants, the ischemic times were significantly longer in the group that received LT post-policy change. EVLP was not used at our program during this period.

Organ cost for transplantation is bundled into an organ acquisition fee that includes expenses related to the procurement team (surgeon, assistant, and staff), travel by private jet, as well as equipment cost for perfusion, preservation, and transportation of the organ. For organs procured as "local" there are two components to the organ cost; the organ acquisition charge from the local OPO and the cost of transportation by land or air. For organs procured from "distant" OPOs there are three components to the organ cost; the organ acquisition cost from the OPO managing the donor, the administrative overhead charge by our local OPO for support provided in coordinating the import event, and the cost of transportation by air (which varies by distance traveled). The median organ cost more than doubled from $34,000 to $70,203 with the policy change. This is understandable in light of the decline in local LT, and the greater resource utilization and transportation cost for organs procured from a distant DSA. These cost data do not reflect two other important expenses. A negative fly out denotes a procuring team flying to a remote donor hospital but declining the organ; this is a largely non-reimbursed activity. The estimated cost of a negative fly out is between $10,000 and $15,000. We noted zero negative fly outs in the pre-policy era versus three in our shorter post-policy era. If the higher negative fly out trend we observed continues, it will increase the acquisition cost for organs and will lead to an overall higher cost for lung transplantation in the future. Finally, local transplants within the DSA are easier to coordinate; 100% of our local LT were performed in the daytime as opposed to 67% with distant donors ($p<0.001$). Daytime interventions utilize significantly fewer resources, cost less, and may have better outcomes than nighttime interventions[8–12].

The new lung allocation policy aims to increase access to organs for waitlist candidates with the greatest severity of illness, and the urgent change was driven by the perception that patients were dying because of arbitrary boundaries. The OPTN report detailing the initial 6 month period post policy change shows no decline in waitlist mortality with the new policy[3].

Furthermore, preliminary data suggest that the policy has not resulted in a change in the type of patients undergoing LT or the early outcomes. However, there has been a significant decline in local LT, a higher organ discard rate, and a higher cost to the system. We have anecdotally noted several episodes since policy change, where our program is procuring lungs by flying out to a neighboring DSA, while a team from a LT program from that DSA is flying in to our facility for a procurement at virtually the same time; the recipients have had very similar lung allocation scores on these occasions. It would be highly informative if future OPTN reports would outline how frequently patients with very similar disease severity are being transplanted in a relatively short time window with organs from each other's DSAs. In addition to the greater cost shown in our study and the issues of logistics and efficiency with fewer local donors, it is possible that access to transplant may be adversely affected. This would be particularly important for patients listed at lower volume programs which may now share overlapping 250 nautical mile circles with one or more larger volume program, with presumably longer lists of potential recipients with higher LAS. Furthermore, patients with emphysema, who typically have lower LAS and largely benefit from LT with improved quality of life, may have an even lower likelihood of being transplanted.

Organ transplantation in the United States is largely a regional healthcare commodity and it is likely that any change in policy may affect centers differently depending upon multiple factors. Our experience as a busy LT program partnering with an OPO that manages donors efficiently and cost-effectively at a specialized facility may be unique, but the concept is becoming increasingly relevant with several other busy OPOs building specialized donor care facilities (personal communication from Gary Marklin, MD, Mid-America Transplant). Additionally BJH recipients reported over this study period had lower LAS compared to national LT recipients and were less likely to be mechanically ventilated. Finally, our negative fly out rate of 0 in the pre policy era may be lower that of other busy LT programs. Both the OPTN and BJH data represent early trends and longer term outcomes remain to be seen.

We foresee some potential solutions to issues that the new policy has created. These solutions are not mutually exclusive. The first involves continuing the wider sharing of organs under the new policy and developing experienced procurement teams within each DSA which would mitigate the need for surgeons from transplanting institutions to fly out to donor hospitals. This will require a significant degree of trust between surgical teams as the final assessment of organ quality hinges upon inspection in the operating room and the situation would be akin to the online purchase of a life-supporting product. Alternatively, the new policy could be modified for application only to the sickest patients on the waitlist. With prior OPTN reports indicating a significantly higher waitlist mortality with LAS≥50[13], using this evidence-based cutoff would be simple to implement and direct resources to those most in need and the somewhat higher cost to the system could be more easily justified. Finally, in a hybrid model, the allocation system could be modified in a way that factors distance into the allocation priority and encourages wider sharing of organs when there are clinically meaningful differences in potential recipients across DSAs. Such a plan should incorporate LAS as well as factors like short recipient height and significant allosensitization, which are barriers to transplantation. Creation of an appropriate hybrid model would necessitate a detailed analysis of OPTN data over the past several years to inform the statistical modeling and though ideal, would be resource intensive and may be difficult to implement. It is encouraging to note that the OPTN is continuing strong efforts to optimize the organ allocation system by inviting public comments on its website and seeking feedback from the community to inform potential modifications to the new lung allocation policy. The issues associated with equitable organ allocation need to be weighed in balance with other parameters. How they balance out should be for the transplant community and not the courts to decide since legal experts stipulating these changes are unlikely to understand the complex environment and the myriad of downstream effects. This is a critical juncture in the field of transplantation and policymakers should choose equitable and sustainable access for this lifesaving discipline.

In conclusion, our as well as national data indicate that the patients being transplanted since lung allocation policy change have largely comparable disease severity. However, the cost of donor lungs has increased substantially due to more organs being procured from distant OPOs. While we await longer-term data on recipient outcomes, our early experience provides an impetus to consider amendments to the new lung allocation policy which are informed by transplant professionals.

Acknowledgments

Varun Puri is supported by NIH K07 CA178120 and Mid-America Transplant Foundation 022017research grants. TS is supported by a Barnes Jewish Hospital Foundation grant. Daniel Kreisel is supported by National Institutes of Health grants 1P01AI116501, R01 HL094601, Veterans Administration Merit Review grant 1I01BX002730 and The Foundation for Barnes-Jewish Hospital. Daniel Kreisel serves on the Scientific Advisory Board of Compass Therapeutics and receives research support from Compass Therapeutics.

Abbreviations:

DSA: Donor Service Area

OPTN: Organ Procurement and Transplantation Network

OPO: Organ Procurement Organization

LT: Lung Transplantation

LAS: Lung Allocation Score

LUR: Lung Utilization Rate

BJH: Barnes Jewish Hospital

DCD: Donation after Cardiac Death

EVLP: Ex-vivo Lung Perfusion

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Table 1:

A comparison of clinical characteristics and organ costs in for lung transplantation at Barnes Jewish Hospital in the pre-policy and post-policy eras.

	Pre-Policy (n=77)	Post-Policy (n=50)	p-value
Donor Characteristics			
Mean age (years)	39.9 ± 15.6	36.5 ± 16.1	0.3
Best PaO2 (mm Hg)	511 ± 65	483 ± 76	0.06
Local donor	58.4% (45)	30.0% (15)	0.002
Recipient Characteristics			
Mean age (years)	55 ± 15	56 ± 13	1.0
Pre-operative mechanical ventilation	9.1% (7)	2.0% (1)	0.15
Mean Lung Allocation Score	45.4 ± 16.9	42.5 ± 12.7	0.2
Median time on waitlist (days)	38, IQR: 11–80	32.5, IQR: 13–96	0.9
Bilateral transplant	96.1% (74)	96.0% (48)	1.0
Mean ischemic time (minutes)	209 ± 64	244 ± 60	0.002
Median length of stay (days)	21, IQR: 14–41	24, IQR: 14–33	0.5
30-day mortality	0% (0)	4% (2)	0.15
90-day mortality	0% (0)	4% (2)	0.15
Grade 2 or 3 PGD at 72 hours	11.7% (9)	8.0% (4)	0.5
Median organ cost	$34,000	$70,203	0.06

PGD=Primary graft dysfunction (reperfusion injury, grade 2 or 3 denote clinically significant lung graft dysfunction), PaO2=Partial pressure of O2 in arterial blood, Marginal donor=Donor not meeting ideal quality criteria of PaO2, chest x-ray, or bronchoscopic findings, IQR=Interquartile range.