

Analyzing the Impact of the Lung Allocation Score on Lung Disease Treatment Using Care Ethics


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On my honor as a University student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments.

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Introduction

In the past 30 years, lung transplantation has maintained its status as a reasonable therapy for patients with a variety of end-stage lung diseases (Egan et al., 2006). Over time, while the demand for new lung transplants has grown, the scarcity of suitable lung donors has remained, necessitating a relatively strict criteria for candidacy. As a result, the Department of Health and Human Services issued the Final Rule, effective March 16, 2000, which set forth new guidelines for the Organ Procurement and Transplantation Network (OPTN) (Colvin-Adams et al., 2012). These guidelines emphasized the broader sharing of organs, reducing the use of waiting time as an allocation criterion, and the creation of a new allocation system that focuses objectively on medical criterion and urgency instead (Egan et al., 2006). In 2005, the OPTN approved the implementation of the lung allocation score (LAS) for lung allocation. The LAS removed waiting time, a criterion for the prior allocation system, and aimed to reduce wait list mortality, prioritize candidates based on urgency, and maximize benefits to recipients (McShane & Jr, 2013). In addition, it intended to minimize the role of geography during the allocation process with respect to ischemic time.

Since the implementation of the LAS, studies have centered on analyzing the impact this allocation system has on waiting list time, waiting list mortality, and posttransplant one-year survival rate (Mooney & Gries, 2015). In addition, to assess the equitable distribution of lungs, research has been done on the survival between white and non-white patients (Liu, 2011). Despite the widespread success seen from the implementation of the LAS, there is limited understanding of the effectiveness of the parameters incorporated into the LAS on the quality of care offered to patients. In neglecting to study the algorithm and constraints of the LAS, it is

difficult to determine if the noted benefits were due to this allocation system or increased regulatory government oversight that coincided with the implementation of the LAS.

Through assessing the current lung allocation system through the lens of care ethics, I aim to assess the quality of care offered to lung transplant patients since the implementation of the LAS. Specifically, I will demonstrate that the current iteration of the LAS algorithm has not altered medical care by failing to address care in three facets: attentiveness, competence, and responsiveness. These inadequacies are demonstrated through the rationale and parameters used to inform the LAS, and ultimately the lung allocation system.

Background

The lung allocation system relies on clinical information from patients 12 years of age and older to determine the most effective and equitable manner in which to make lung offers to patients (United Network for Organ Sharing, n.d.). These considerations include lab values, test results, and physician diagnoses. Since its implementation, the LAS has undergone a series of revisions which include the addition of the partial pressure of carbon dioxide in 2007; bilirubin concentration in 2008; and, most recently, total bilirubin, cardiac index, and central venous pressure in 2015 (Mooney & Gries, 2015). These parameters are used in a formula to estimate the candidate's medical urgency and post-transplantation survival probability. This results in a LAS with a raw score between -730 and 365, which is then converted to a normalized lung allocation score between 0 and 100. A higher LAS indicates a greater benefit from transplantation relative to current care and a higher priority for lung transplantation.

Literature Review

Numerous past studies have attempted to assess the improvement in care afforded by the current lung allocation system since its implementation. However, these studies attributed

improvements and downfalls of the new lung allocation system to the compliance/non-compliance of physicians participating in the new system, as opposed to the constraints and oversights imposed by the creators of the LAS itself. However, even when the parameters of the LAS were studied as the main cause of the system's shortcomings, it was presented as a non-urgent supplement that would only bolster existing conclusions for one-year survival rates, as opposed to considering the long-term survival rates. Therefore, these studies are unable to make clear conclusions on the improvement of medical care offered to lung disease patients.

In Effect of lung transplantation on health-related quality of life in the era of the lung allocation score: A U.S. prospective cohort study, first author J.P. Singer studied the long-term implications of the LAS system on patients' health-related quality of life (HRQL) after lung transplantation (Singer et al., 2017). While typical studies relied on one-year survival rates, Singer's study attempted to understand long-term implications of the LAS system by investigating a cohort of patients who had survived up to three years past transplantation. Singer found that lung transplants improved HRQL in all studied categories, some of which were parameters for the LAS, but noted improvements were not as stark for patients 65 years and older. In general, patients over the age of 65 face a medical survival time of 3.5 years – a full three years less than patients younger than 50 years old. Instead of attributing this finding to the poor predictive capability of the LAS, Singer focuses on individual health domains important to lung transplants, such as depression, anxiety, symptom burden, and cognitive impairment, for physicians to consider when developing treatment plans to improve HRQL. Therefore, this study chose to place the burden of poor outcomes of lung transplants for patients aged 65 and older on physicians who focused solely on the quantitative metrics of lung transplant candidacy instead of accounting for the patient-centered metrics of transplant efficacy as well.

Meanwhile, in her study *Cystic fibrosis physicians' perspectives on the timing of referral for lung transplant evaluation: A survey of physicians in the United States*, Kathleen J. Ramos surveyed physicians associated with Cystic Fibrosis Foundation-accredited care centers in the U.S. during the post-LAS era (Ramos et al., 2017). Through her study, Ramos attempted to understand physicians' rationale for referring patients for a lung transplant evaluation and its respective timing following diagnosis of an advanced lung disease. This study's survey uncovered that nearly 54% of respondents would not recommend patients with pulmonary hypertension for a lung transplant referral, despite it being an internationally recognized indication to list a patient for a lung transplant – not just a referral. Through this evaluation, Ramos, like Singer, is attributing physicians' individual behaviors as a root cause for the poor outcomes of lung transplants during the post-LAS era, as opposed to any issues with the LAS system in predicting post-transplant survival or equitably distributing lungs to the sickest individuals.

Ramos also reported that only 15% of the survey's respondents employ components of the LAS to determine timing for lung transplant referrals (Ramos et al., 2017). Ramos attempts to justify this insufficient use of the LAS by stating physicians rely heavily on other factors such as lung function for referral. Per Ramos, this practice results from a lack of knowledge of the various parameters incorporated in the LAS and referral practices that are informed by clinical experience as opposed to published research. Once again, Ramos attributes missed referral opportunities and the untimely deaths of cystic fibrosis patients to physician behaviors, as opposed to the algorithmic predictions for wait list survival and post-transplantation survival provided by the LAS system.

While prior studies shed light on the various determinants of health, particularly as it relates to the ability of physicians to alter care, the negligence of assessing the care provided since the implementation of the LAS prevents future alteration of the system and the ability to provide equitable care to all patients. Subsequently, this paper will not only highlight how the current allocation system fails to meet the OPTN's original goals, but will also leverage care ethics to demonstrate the lack of improvement in medical care offered directly to lung disease patients since the implementation of the LAS.

Conceptual Framework

My analysis of the quality of care in the post-LAS era draws upon facets of care ethics, which allows me to assess how interpersonal relationships and empathy impact the decision-making capability of the LAS system and its users. Inspired by the work of Carol Gilligan, care ethics is an ethical framework that emphasizes the importance of relationships and stresses that the development of morals does not occur by learning about moral principles (van de Poel & Royakkers, 2011). This framework, instead, states that by recognizing the vulnerability of the other and by placing themselves in his or her shoes, people can learn what is good or bad at a particular time. This is especially important in situations with asymmetrical relationships such as those between physicians and patients.

In care ethics, care is defined as, "a species activity that includes everything that we do to maintain, continue, and repair our 'world' so that we can live in it as well as possible" (Tronto, 1998). Thus, care can be represented through our actions. However, care can also be presented through our attitude as concern, compassion, and empathy. With regards to engineering practice, care ethics can also emphasize social ethics of engineering and social responsibility (van de Poel & Royakkers, 2011). For example, large companies exist at the intersection of different

relationships, with each relationship having diverse, and sometimes contradictory, expectations. Thus, each member of the company/institution must manage these various interests through an attitude of compassion, attention, and care.

As care can be presented through actions and attitudes, the practice of care encompasses four distinct facets: attentiveness, responsibility, competence, and responsiveness (Tronto, 1998). Attentiveness raises questions such as what care is necessary, and who gets to articulate the needs and say which problems should be cared about? Responsibility presents questions such as who should be responsible for meeting the needs for care that do exist, and how should such responsibility be fixed? Competence asks who are the caregivers and how effective are they at their jobs? Lastly, responsiveness questions how care receivers respond to the care that they are given and how well does the care process meet their needs?

In the analysis that follows, I will leverage care ethics to shed light on the limited change in the quality of medical care in the United States following the implementation of the LAS algorithm for lung allocation. I will do this by identifying and analyzing parameters and constraints of the current LAS system with respect to three facets of care ethics: attentiveness, competence, and responsiveness.

Analysis of Evidence

The systems and biomedical engineers responsible for designing the lung allocation algorithm did not thoroughly consider three aspects of care - attentiveness, competence, and responsiveness. The negligence of these components of care when categorizing care as social responsibilities, actions, and attitudes is evident in the parameters and constraints incorporated into the LAS system. Given that care ethics provides a framework through which the diverse needs of stakeholders in a large enterprise can be managed, it follows that without the

consideration of these facets of care, the LAS system fails to improve the quality of medical care available to lung transplant candidates. As Tronto mentions, caring should take place in an environment where all those involved in caring can contribute to the ongoing discussion of caring needs and how to meet them (Tronto, 1998). Therefore, an accurate illustration of the effectiveness of the LAS system cannot be accounted for without considering the inherent deficiencies of care built into the system by its original developers. In the following analysis, I will highlight three constraints of the LAS system that reflect the inadequate consideration of care with regards to attentiveness, competence, and responsiveness.

Practicing Care Through Attentiveness

A. What is involved in the LAS calculation?

The LAS involves the following steps:

1. Calculate the waiting list survival probability during the next year
2. Calculate the waitlist urgency measure
3. Calculate the post-transplant survival probability during the first post-transplant year
4. Calculate the post-transplant survival measure
5. Calculate the raw allocation score
6. Normalize the raw allocation score to obtain the LAS.

B. The *transplant benefit measure* for candidate *i* (Benefit_{*i*}) is:

$$\begin{aligned}
 \text{Benefit}_i &= PT_i - WL_i \\
 &= \text{expected days lived during 1}^{\text{st}} \text{ year post-transplant} - \\
 &\quad \text{expected days lived during additional year on waiting list} \\
 &= \text{additional days of life lived with a transplant} \\
 &\quad \text{than without a transplant}
 \end{aligned}$$

Figure 1. A) Components of the lung allocation score. The three overarching measures are waiting list urgency, post-transplant survival, and transplant benefit (United Network for Organ Sharing, 2009). **B) Transplant benefit measure.** Used to calculate the raw lung allocation score (United Network for Organ Sharing, 2009).

Through failing to incorporate attentiveness while practicing care, the designers of the LAS did not alter the quality of medical care as was demonstrated by an increase in resource utilization and poor long-term post-transplantation survival for lung transplant candidates in the United States. Attentiveness in care is achieved by considering the need for care, along with who gets to dictate the nature of the needs and how they are addressed (Tronto, 1998). In the context of the current lung allocation system, the LAS leverages inputted medical diagnoses, lab values,

and physiologic condition parameters to determine three overarching measures: waiting list survival, waiting list urgency, and one-year post-transplant survival, as seen in Figure 1A (Mooney & Gries, 2015).

The difference between the post-transplant survival measure and the waiting list urgency measure produces a value known as the transplant benefit (Figure 1B) (United Network for Organ Sharing, 2009). This parameter indicates the additional number of days a patient would live if granted a transplant relative to if they did not receive a transplant. While on the surface this metric appears to aid in determining lung allocations to patients with the greatest chances for post-transplantation survival, and thus limit futile transplants, this metric fails to account for the quality of life in the days following the transplantation. For many patients, a change in lifestyle is a major desire when deciding to pursue a lung transplant. Thus, failing to account for the quality of life afterwards demonstrates a failure in practicing attentiveness in deciding the needs for patients' care. Furthermore, it grants the LAS algorithm the ability to determine the nature of patients' posttransplant care needs, as opposed to the patients themselves or their physicians. This lack of attentiveness was seen by a significant increase in resource utilization following implementation of the LAS system, which includes increases in hospital charges, length of stay, discharge disposition to non-home, and tracheostomy use (Maxwell et al., 2014).

Therefore, by failing to account for the quality of life that follows transplantation, developers of the LAS system failed to satisfy attentiveness when practicing care. Attentiveness works to provide a thorough assessment of the care recipients' needs and assign the duty of identifying needs to care givers. Therefore, through its use as a determinant for lung allocation, this allocation system robs patients and physicians the ability to make an informed decision regarding the quality of patients' life post-transplantation.

Practicing Care Through Competence

While the quality of medical care offered to lung transplant candidates is an essential component in improving transplant survival, the LAS system also aims to make lung allocation more equitable and reduce waiting times across the country. However, despite the effort to practice equitable care, the developers of the LAS system are deficient in competence. To reiterate, competence is a component of care that questions how well care givers do their work and if there are any existing conflicts between care givers and care receivers (Tronto, 1998). Through the LAS system, the OPTN – the care givers who are responsible for the distribution of donor lungs – fail to serve their social responsibility of care due to a lack of competence in ensuring a geographically equitable distribution of donor lungs.

In addition to the LAS, the current allocation policy depends on primary factors such as geography, blood type, and age computability, along with secondary factors such as thoracic cavity size match between donors and recipients (Colvin-Adams et al., 2012). Geographic location, in particular, is crucial to reduce ischemic times. As a result, lungs are first offered locally, and then to candidates outside of the local area who are in defined zones outside of the donor hospital. Local is defined as within the organ procurement organization's (OPO) donation service area (DSA). The OPTN and United Network for Organ Sharing (UNOS) have defined zones outside of the DSA as: A (0-500 miles, nonlocal), B (501-1000 miles), C (1001-1500 miles), D (1501-2500 miles), and E (>2500 miles).

As a result of this policy, lung donations can be preferentially offered to patients hundreds of miles away, sometimes even outside of the bounds of zone A, simply because of the predefined borders of the DSA. This system, consequently, results in greater travel of a donated organ to patients with a lower LAS even in cases where there are patients closer to the OPO with

a higher LAS. This discrepancy means that the OPTN is not efficiently or equitably distributing donor lungs in the post-LAS era, thereby lowering the system's competence in providing care.

A retrospective analysis of all the double lung transplants (DLT) performed in 2009 counted the number of *events* where an ABO blood group-matched, size-matched DLT candidate existed regionally with a higher LAS than the local candidate who eventually received the organs (Russo et al., 2013). Of the 580 locally designated lung donations, there were 3,454 events where a local DLT recipient was preferred over a regional candidate with a higher LAS. Furthermore, 16.1% of events resulted in the death of a patient on the waiting list. As a result, the researchers concluded that the locally based lung allocation system currently employed results in a higher frequency of events where an organ is allocated to a local individual with a lower LAS in the presence of an appropriately matched regional candidate with a higher LAS.

These studies highlight the deficit of competence within the existing LAS system in accomplishing its overarching care goals of creating a boarder system for organ sharing and equitably allocating organs on the basis of medical urgency (Egan et al., 2006). The inability of the OPTN to approve and utilize a system that is successful in satisfying the care needs of lung transplant candidates prevents the LAS system from being widely effective in altering the quality of care offered to lung disease patients.

Practicing Care Through Responsiveness

The third component of care lacking in the current iteration of the LAS system is responsiveness. As defined by care ethics, responsiveness questions how care receivers respond to the care they are given. There is no consideration in the current system for the survival outcomes of patients who undergo the transplants. Through assessing the post-transplantation survival one-year following the procedure and at time spans greater than that, then along with the

predictive capability of LAS parameters, the poor responsiveness of patients to the care afforded by the new LAS system can be identified.

Within the LAS algorithm, the post-transplant survival only predicts survival for one year after the transplantation and assumes that survival probabilities remain

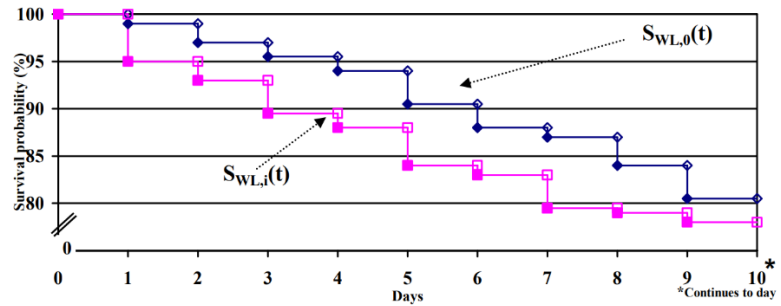


Figure 2. Waitlist survival probability distribution as a function of time. The graph for the post-transplant survival has the have stepwise appearance (United Network for Organ Sharing, 2009).

constant for 24-hour intervals throughout that one year (Figure 2) (United Network for Organ Sharing, 2009). Therefore, not only is there a lack of consideration for the long-term care patients may need following transplantation, but there is also a thorough inconsideration for the immediate needs patients may have in the hours, days, and weeks that follow transplantation.

A study investigated the short-term transplantation outcomes during the pre-LAS era and post-LAS era (Kozower et al., 2008). It was found that there was no change in hospital mortality and 1-year survival between the two cohorts. However, it was uncovered that post-operatively, patients in the post-LAS era suffered significantly from increasing rates of graft dysfunction and spent longer in the ICU. Therefore, the responsiveness of these patients to the care afforded by the new LAS system failed to indicate any major changes, and instead worsened the quality of post-operative care.

Additionally, an analysis of the long-term survival in the post-LAS era showed a significant increase in mortality in the two months immediately after the one-year threshold, which was not present in the pre-LAS era (Maxwell et al., 2014). Prior studies have also shed light on the ineffectiveness of the current parameters to predict long-term survival, stating

i LAS results should not be considered definitive; they are merely a snapshot based upon the values entered and can vary daily.

Date of Birth * (mm/dd/yyyy)

Height * ft in
 cm

Weight * lbs
 kg

Lung diagnosis code *

Functional status

Diabetes

Assisted ventilation

Requires supplemental O₂

Predicted FVC Percentage (%) 6-minute walk distance (feet)

Pulmonary Artery Systolic Pressure (mmHg) Mean Pulmonary Artery Pressure (mmHg)

Cardiac index (CI) (L·min/m²) Central venous pressure (CVP) (mmHg)

i If using a central venous test value for PCO₂: subtract 6 mmHg before entering the value.

PCO₂ (mmHg)
 Current
 Highest
 Lowest

Serum Creatinine (mg/dL)
 Current
 Highest
 Lowest

Total Bilirubin (mg/dL)
 Current
 Highest
 Lowest

[Reset](#) [Calculate](#)

Figure 3. LAS calculator provided by OPTN within the Department of Health and Human Services (*LAS Calculator - OPTN, n.d.*).

its impact, it should be acknowledged that this system has greatly reduced waiting list mortality through a reduction in waitlist time and increased transplant opportunities for patients diagnosed with idiopathic pulmonary fibrosis (IPF) (McCue et al., 2008). With previous allocation systems

the “5-year survival rate was not much better than chance” (Gries et al., 2010). Particularly, the inability to state the severity of comorbidities, such as diabetes and hypertension, in the LAS calculator makes it difficult to assume patients’ responsiveness to care during the transplantation process (Figure 3). These findings underscore the limited predictive capability of current LAS parameters seen in Figure 3 to assess long-term transplant survival. Simply put, the care receivers are not responding to the new care at a markedly increased level that would demonstrate the benefits of the LAS system, thus limiting the quality of care afforded by this system.

While the lack of improvement in clinical outcomes following the implementation of the LAS system lessens

that depended on accumulated waitlist time, patients with non-chronic lung diseases, such as IPF, were disadvantaged because they did not spend as much time on the transplant list as other patients with chronic illnesses. However, while the number of IPF patients receiving lung transplants has significantly increased under the new LAS system, there is limited evidence to suggest that the survival following transplantation of IPF patients has improved, both one-year after and greater than three-years after transplantation ((De Oliveira et al., 2012; Merlo et al., 2009). This is in the context of the use of a post-transplantation survival metric in the LAS that aims to optimize lung allocation to individuals with the greatest chance for survival. Per care ethics, responsiveness questions how care receivers respond to the care they are given. Therefore, this lack of improvement in IPF patient mortality after lung transplantation highlights that the LAS system is not increasing patients' responsiveness to treatment plans, and is thus not an effective care system to meet patients' needs and improve clinical outcomes.

Conclusion

Although there is limited information available to justify the various assumptions and decisions made by developers of the LAS algorithm, the overall effectiveness of this system in providing equitable and improved medical care can be assessed through the care ethics. Through understanding the shortcomings of the LAS system since its implementation in 2005 with regards to three facts of care – attentiveness, competence, and responsiveness – the ability of this allocation system to achieve its goals can be understood. Following analysis with care ethics, it can be concluded that the current iteration of the LAS system fails to improve clinical outcomes relative to the pre-LAS era, and therefore does not improve the quality of care available to lung disease patients.

This new approach to understanding the effectiveness of the LAS system is crucial as other countries internationally are beginning to adopt similar allocation systems that depend on the LAS. Notably, Germany in December 2011 adopted a new allocation scheme based on the LAS (Gottlieb et al., 2014). Therefore, by employing this new viewpoint to the LAS, the UNOS and OPTN can leverage its influence to disseminate an equitable and beneficial lung allocation system internationally.

Word Count: 3731

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