

Starting a Lung Transplant Program

A Roadmap for Long-term Excellence

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Lung transplantation is an effective therapy for many patients with end-stage lung disease. Few centers across the United States offer this therapy, as a successful lung transplant program requires significant institutional resources and specialized personnel. Analysis of the United Network of Organ Sharing database reveals that the failure rate of new programs exceeds 40%. These data suggest that an accurate assessment of program viability as well as a strategy to continuously assess defined quality measures is needed. As part of strategic planning, regional availability of recipient and donors should be assessed. Additionally, analysis of institutional expertise at the physician, support staff, financial, and administrative levels is necessary. In May of 2007, we started a new lung transplant program at the University of Iowa Hospitals and Clinics and have performed 101 transplants with an average recipient 1-year survival of 91%, placing our program among the top in the country for the past 5 years. Herein, we review internal and external factors that impact the viability of a new lung transplant program. We discuss the use of four prospectively identified quality measures: volume, recipient outcomes, financial solvency, and academic contribution as one approach to achieve programmatic excellence. CHEST 2015; 147(5):1435-1443

ABBREVIATIONS: CMS = Centers for Medicare and Medicaid Services; DSA = designated service area; FTE = full-time equivalent; ISHLT = International Society for Heart and Lung Transplantation; LAS = lung allocation score; OPO = Organ Procurement Organization; OPTN = Organ Procurement and Transplant Network; QAPI = Quality Assessment and Performance Improvement; ROOT = Report of Organs Offered and Transplanted; SRTR = Scientific Registry of Transplant Recipients; UNOS = United Network of Organ Sharing

The field of lung transplantation has developed rapidly over the past 25 years from only 45 transplants performed worldwide in 1987 to > 3,700 transplants alone in 2011.¹

The clinical success of lung transplantation in recent years can be attributed to advances in surgical techniques, immunosuppressive regimens, and refinement of donor and

Manuscript received September 9, 2014; revision accepted January 18, 2015.

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FUNDING/SUPPORT: This work was supported by the National Institutes of Health/National Heart, Lung, and Blood Institute [Grant K08 HL114725-01 to Dr Parekh], the American Heart Association [Grant 0675028N to Dr Klesney-Tait], the Institute for Clinical and Translational Science at the University of Iowa via the National Institutes of

Health Clinical and Translational Science Award program [Grant 3UL1RR024979-03S3 to Dr Parekh and 2UL1TR000442-06 to Dr Eberlein]. United Network of Organ Sharing data in this work was supported in part by Health Resources and Services Administration [Contract 234-2005-37011C].

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DOI: 10.1378/chest.14-2241

recipient selection criteria. Despite transplantation of increasingly older and sicker patients, lung transplant recipients have a 1-year survival rate > 87% and median survival of > 6 years in the most recent International Society for Heart and Lung Transplantation (ISHLT) Registry Report.¹ Moreover, lung transplantation is associated with a dramatic and sustained improvement in health-related quality of life.^{2,3} Although solid organ transplantation is performed at 248 different centers across the country, only 27% of these programs offer lung transplant.⁴

In the United States, 124 institutions have opened lung transplant programs since 1988; however, only 66 of these programs are currently performing lung transplants,

representing a 44% closure rate.⁴ This surprising statistic reflects the challenges associated with establishing and maintaining a viable lung transplant program. Thus, a systematic evaluation of regional need, local expertise, and institutional resources is beneficial to any center considering the addition of a lung transplant program.

In 2007, the University of Iowa Hospitals and Clinics established a lung transplant program, which has been successful as measured by volumes, patient outcomes, financial solvency, and academic productivity. Herein we present one generally applicable strategy to develop a durable lung transplant program. We validate our approach with an assessment of the University of Iowa Lung Transplant Program.

Materials and Methods

Study Population

Our source population consisted of the first 101 patients who underwent transplantation at the University of Iowa between May 2007 and

July 2014. The Scientific Registry of Transplant Recipients (SRTR) database was used to benchmark University of Iowa recipient outcomes against national recipient outcomes.

Results and Discussion

Assessment of Program Viability

Volume: *Why Does Volume Matter?* A transplant program must maintain minimum yearly volumes for several reasons: (1) link between frequency and competency for both physicians and support staff in the care of patients with complex medical conditions,⁵⁻⁷ (2) Centers for Medicare and Medicaid Services (CMS) mandated volume requirements for program certification,⁸ (3) private insurers often have volume requirements, and (4) there must be a sufficient number of cases to financially support specialized personnel.

Programmatic volumes are driven by the potential donor and recipient pools. For a new program to be successful, it must address a gap in available service for patients with end-stage lung disease in the region who may benefit from access to a transplant program. Additionally, the program must have access to a sufficiently large pool of acceptable lung donors.

Recipients Volumes:

Geographic Constraints: Logistical constraints and organ preservation limitations require most lung recipients to live within 4 to 5 h of the center. Therefore, a new center has a local recipient catchment area of approximately 350 nautical miles. Patient relocation is a possibility for a small percentage of potential recipients, as is on-call air travel, but these arrangements are not common,

particularly for a new center. Institutions can estimate the volume of potential recipients using population density information in conjunction with available transplant actuarial data (Table 1).⁹ If other centers are active in that catchment area, the actual number of available recipients for any one center will be decreased.

Recruitment: Institutional programs in interstitial lung disease, cystic fibrosis, COPD, and pulmonary hypertension are important to identify patients regionally who may benefit from transplantation. Additionally, collaborative relationships with referring physicians in the catchment area are necessary. Finally, institutional contracts with insurers are needed for patients to be evaluated and ultimately receive transplants.

Recipient Selection: ISHLT provides general guidance regarding suitability of recipient characteristic; however, centers vary broadly in their individual criteria for listing.¹⁰ Centers willing to list extended criteria recipients (obese, limited functional status, patient supported with mechanical ventilation or extracorporeal membrane oxygenation, high-risk pathogen infections like *Burkholderia cepacia* complex) will have a larger pool of recipients than centers that do not accept these patients. However, the Medical and Surgical Directors must weigh these programmatic risks carefully using SRTR data regularly to assess the programmatic effects of such decisions (see Institutional Expertise section).¹¹⁻¹⁵

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