Starting a Lung Transplant Program

A Roadmap for Long-term Excellence

Julia Klesney-Tait, MD, PhD; Michael Eberlein, MD, PhD; Lois Geist, MD, FCCP; John Keech, MD; Joseph Zabner, MD; Peter J. Gruber, MD, PhD; Mark D. Iannettoni, MD, MBA; and Kalpaj Parekh, MD

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.

AFFILIATIONS: From the Department of Internal Medicine (Drs Klesney-Tait, Eberlein, Geist, and Zabner) and the Department of Cardiothoracic Surgery (Drs Keech, Gruber, and Parekh), University of Iowa Carver College of Medicine, and the Veterans Affairs Medical Center (Drs Geist, Keech, and Parekh), Iowa City, IA; and the Department of Cardiovascular Sciences (Dr Iannettoni), East Carolina University, Greenville, NC.

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].

CORRESPONDENCE TO: Julia Klesney-Tait, MD, PhD, Department of Internal Medicine, Roy J. and Lucille A. Carver College of Medicine, University of Iowa, 200 Hawkins Dr, Iowa City, IA 52242; e-mail: julia-klesney-tait@uiowa.edu

© 2015 AMERICAN COLLEGE OF CHEST PHYSICIANS. Reproduction of this article is prohibited without written permission from the American College of Chest Physicians. See online for more details.

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

TABLE 1] Estimated Need for Lung Transplantation in State of Iowa

Recipient Age, y	US Lung Transplant Use per Million Population			Iowa Lung Transplant Use	
	Single Lung Transplant	Bilateral Lung Transplant	Total Lung Transplant	Iowa Population	Annual Iowa Need
< 65	2.36	2.71	5.07	2.5×10^6	12.7
> 65	4.54	1.14	5.68	4.5×10^5	2.6
Total	6.9	3.85	10.75	3×10^6	15.3

Data extrapolated from the 2005 Organ, Tissue, and Transplant report by Ortner⁹ shows the number of single and bilateral lung transplants in the United States per million broken down by age <65 or >65 y. For Iowa use estimates, single and bilateral lung transplant were combined. The percentage of people >65 y was obtained from US Census Bureau data.

Donors Volumes:

Allocation: Donor lung allocation is determined by three main parameters: geographic location, followed by blood group and lung allocation score (LAS) as outlined by Organ Procurement and Transplant Network (OPTN) policy.¹⁶⁻¹⁹ Organs are initially offered to recipients within the local Organ Procurement Organization's (OPO) designated service area (DSA). OPOs are responsible for identifying donor organs within their assigned geographic area (DSA) and then allocating these organs based first on blood group and then by LAS. To receive organ offers, recipients must be registered with the United Network of Organ Sharing (UNOS). At registration, the recipient LAS is determined by an equation that estimates medical urgency and expected outcome.²⁰ For recipients in the same blood group, priority is given to the person with the highest LAS in that particular DSA. If no one with that matching blood group can use the organs, then the organs are offered by LAS to compatible blood group recipients in that DSA. The local lung center has the ability to use donors from their OPO for any compatible recipient on their list prior to those organs being offered to other centers outside of their OPO. For centers that share an OPO, organs would be offered based on recipient LAS for all centers in that OPO before being offered to other centers. A new program in a shared OPO would need to either have patients with higher LAS on their list or accept offers deemed unacceptable by other centers that share their OPO to receive offers in this scenario. Thus, understanding donor access regulations is an important part of programmatic planning, and an experienced surgical and medical team is required to make these assessments. If the donor lungs cannot be used in the local OPO, they are offered out to other centers in 805-km radii from the donor hospital by recipient LAS until they are placed.

Donor Criteria: The availability of suitable organs remains a significant issue in solid organ transplantation, particu-

larly in lung transplant, where only 15% to 20% of potential lungs are used.²¹ Standard donor criteria identify ideal organs; however, most centers consider extended criteria donors routinely.²²⁻²⁵ Willingness to accept extended donors (lung contusion, pneumonia, extensive smoking history), donor after cardiocirculatory death donors, Centers for Disease Control and Prevention high-risk donors, and lungs assessed by ex vivo lung perfusion can increase the number of available organs for a program.

Local OPO Assessment: A strong local OPO is important. The more donor lungs available in the local OPO, the more transplants the local center can potentially perform. Lung-protective management protocols must be in place to maximize organ recovery.

Import Offers: Import offers represent organs from an outside OPO. These organs have either been turned down by the local program(s) or are from OPOs that do not have an active lung program. The importing center must have the infrastructure needed to fly its own surgical personnel to the donor hospital to procure these organs. The availability of these import offers is largely predicted by population density and characteristics of other active programs in the region.

Institutional Expertise: *Esprit de corps:* By necessity, lung transplantation practices are driven largely by experience rather than evidenced-based medicine. Therefore, the Medical and Surgical Directors need to have a shared philosophy regarding donor and recipient selection and management.

The LAS system, adopted in 2005, provides an additional challenge for new programs. A new program that chooses to list very-high-acuity patients risks poor outcomes that can jeopardize insurance contracts and CMS certification.¹⁵ Conversely, conservative listing practices risk low volumes, financial insolvency, and referring physician dissatisfaction. Programmatic leaders must balance patient acuity with ethical considerations

regarding organ use, patient outcomes, program viability, and financial constraints.

Multidisciplinary Team: Patient complexity as well as transplantation regulatory bodies (OPTN, UNOS, and CMS) dictate many of the members of the multidisciplinary team (Table 2).^{8,26} The program, by CMS and UNOS rule, must be staffed to provide continuous coverage (365 days a year, 7 days a week, 24 h a day) by qualified personnel to allow for maximal organ use. Additional information regarding staffing estimates can be obtained from the UNOS-sponsored transplant program survey. This is a voluntary survey that records center-specific data on full-time equivalents (FTEs) used as it relates to center volume.²⁷ See Table 2 legend for Iowa specific staffing data.

Institutional Administrative Support: Finally, institutional expertise in organ transplantation is needed for compliance, support of the Quality Assessment and Performance Improvement (QAPI) (mandated by CMS), and financial analysis of the program. SRTR data are used in multiple formats that are critical for programmatic success. Appropriately educated and prepared staff is necessary to routinely input SRTR data elements used to calculate programmatic characteristics, such as transplant rates, expected vs observed mortality, and organ use.

TABLE 2] UNOS and CMS Requirements for Lung Transplant Programs

Multidisciplinary Team	UNOS Certification Required	CMS Condition of Participation
Transplant pulmonologists	Yes	Yes
Cardiothoracic surgeons	Yes	Yes
Transplant nursing coordinators	Yes	Yes
Transplant pharmacy	Yes	Yes
Transplant social work	Yes	Yes
Transplant psychology	Yes	Yes
Physical therapy	Yes	No
Transplant financial	Yes	Yes
Transplant nutrition	No	Yes

The Iowa experience suggests that initially 2 FTE pulmonary, 0.8 FTE surgery (additional defined donor harvest coverage required), 1.5 FTE nursing, 0.5 FTE medical assistant, 0.5 FTE pharmacy, 0.5 FTE social work, 0.2 FTE psychology, 0.6 FTE secretary, 0.6 FTE data management, 0.2 FTE Quality Assessment and Performance Improvement administration, 0.3 FTE financial coordinator are sufficient for a program that performs 10-15 transplants/y. Additional staffing for growth targets is needed, and, as CMS requirements change, additional data support necessary. CMS = Centers for Medicare and Medicaid Services; FTE = full-time equivalent; UNOS = United Network of Organ Sharing.

Workflows between program physicians and data entry staff (whether coordinators or dedicated data entry staff) are necessary to ensure that there is clear understanding of the “source of truth” for all data elements and for resolution of any data conflicts. It is critically important for program leadership, both clinical and administrative, to be aware of what data are being entered into the system. These program-specific data are analyzed by OPTN/CMS and published semiannually on the SRTR website.

Moreover, in January 2014, SRTR started using the same data to generate cumulative summation technique charts. These charts allow individual programs to monitor their risk-adjusted outcomes in near real time using the same SRTR dataset.²⁸ This information is designed to allow centers to identify potentially deleterious patterns and design quality-improvement projects or alter practices that may be placing center outcomes at risk.

Additional administrative support is also required to comply with CMS-mandated quality programs (two projects are required for each phase of transplantation: pretransplant, transplant, posttransplant). As of January 2014, CMS initiated a focused QAPI survey to provide an in-depth analysis of QAPI activities (as per 42 CFR 482.96 QAPI Conditions of Participation) within the transplant program.²⁹ This quality-focused inspection will specifically assess programmatic use of stated quality projects.

From a financial perspective, CMS certification is required for programs to be paid by CMS to perform transplants in CMS-eligible patients. CMS requires that a minimum number of transplants be performed (10 per rolling calendar year) and that recipient 1-year survival is the same or better than the national 1-year survival based on SRTR-reported data.^{8,30} CMS will not cover any transplants done at that center until a site visit is completed and passed, even if the inspection cannot be performed for months after eligibility. Moreover, CMS certification allows an institution to submit an Organ Acquisition Cost Report to CMS that reimburses the hospital system for approved unpaid CMS patient pretransplant expenses, including organ procurement costs, pretransplant physician and support staff time, and pretransplant evaluation-related testing.⁸ CMS certification is a critical component of programmatic durability in terms of its effect on access to recipients and programmatic financial viability. Therefore, a new program should have the resources to perform some number of unreimbursed transplants to facilitate CMS certification.

University of Iowa Experience: Programmatic Strategy: Our pre-programmatic viability analysis included an assessment of potential volumes and institutional expertise. We then selected four measures of programmatic success and devised strategies to develop and evaluate our progress in these areas: volume, outcomes, financial solvency, and academic research contributions.

Volume:

(1) *Potential Recipients:* Local population and actuarial data were used to project annual number of lung transplant recipients (Table 2). This analysis estimated that annual resident recipient need in Iowa was approximately 15 patients.

Referrals: Timely evaluation was one of our goals for patient and provider satisfaction. We tracked three phases in the referral process on a quarterly basis: number of referrals, time from referral to records obtained, time to first office appointment, and time to transplant listing decision. This analysis allowed us to identify inefficiencies in our process and make changes. UNOS database was used to identify Iowa recipients receiving transplants elsewhere to pinpoint geographic areas in the state that may benefit from additional outreach efforts. Using this approach, we have consistently increased our referral volumes and expanded our catchment area (Fig 1).

Recipient Selection: Our program in general follows the recommendations of the ISHLT position statement regarding patient listing criteria.¹⁰ We have a strictly enforced pulmonary rehabilitation policy for ambulatory

patients requiring documented exercise 5 d/wk; in general this is 30 min on the treadmill, although occasionally for patients who cannot maintain saturation above 88% on facemask oxygen we will use NuStep. Our BMI maximum for listing is 30 kg/m², and minimum is 18 kg/m². We individually consider patients who are ventilated, patients receiving extracorporeal membrane oxygenation, and patients receiving repeat transplants. We have a large population with cystic fibrosis, and we do perform transplants on patients with *B cepacia* complex if it is a low-risk genomovar. Patients over the age of 65 years must have limited comorbid conditions to be considered for listing at our center.

(2) *Donor Volumes:* Historic analysis of donated organs in our OPO indicated that sufficient organs were available regionally.³¹ We then designed a program to maximize lung recovery from potential donors. A best practice protocol for optimal donor management was developed in collaboration with our OPO to provide optimal lung-protective management. All donor cases were reviewed in a quarterly meeting to assess protocol adherence and discuss potential ways to improve organ recovery. Physicians from lung transplant and critical care intensivists as well as Iowa Donor Network staff who manage the donors attended, providing an opportunity for team building and collaboration around a shared mission.

To maximize our ability to recover import offers, we staff these calls with experienced transplant physicians. By using physicians in the program familiar with the potential recipients, we are able to match donor-recipient risk profiles to maximize offer use. Additionally, as experienced critical care physicians, we actively manage potential donor lungs to maximize the chances of successful organ recovery.³²

The UNOS Report of Organs Offered and Transplanted (ROOT) is reviewed quarterly by our physician group. This report can potentially identify organs that were actually suitable for transplantation (ie, recipient survived to 1 year) and conversely organs that may have been unsuitable for transplant (ie, recipient died). We code our refusals systematically so that we can evaluate the reason(s) for refusal. Our goal is to expand the number of organs accepted without compromising our 1-year outcomes (Table 3). Currently, recipient survival at other centers after transplant with organs that we have refused is much lower than our programmatic outcomes, indicating to us that at this point our refusals are

Figure 1 – University of Iowa lung transplant patient referrals by fiscal year.

TABLE 3] UNOS ROOT for University of Iowa Lung Transplant Program 2010-2012

Year	Offered Accepted	Offer Not Accepted	1-y Graft Survival of Organs Declined by Iowa (Best Case), %	SRTR 1-y Survival, %	Iowa 1-y Survival, %
2010	20	25	76	83	92
2011	15	33	70	84	93
2012	10	32	69	85	93

Data from UNOS (<https://portal.UNOS.org> data reports). ROOT, available to all programs from UNOS, provides centers with a list of offers that were declined by their center and used by another center, along with the recipient survival data associated with those organs. ROOT = Report on Organs Offered and Transplanted. See Table 2 legend for expansion of other abbreviation.

consistent with our programmatic goals. Of course, this analysis does have some limitations, as there are reasons for recipient death that are not accounted for in the ROOT that may be unrelated to donor organ quality.

Outcomes: Successful implementation of a new program requires both rapid growth and sustained excellent recipient outcomes (Fig 2). For the first 2 years, our 1-year recipient survival was 100% and has remained above the national average (Fig 2A). Similarly, 3-year recipient survivals are excellent (Fig 2B). Early on in the program, intense involvement of attending staff was required. For the first 2 years, the programmatic directors took almost continuous call. This was exhausting and unreimbursed, but we believed it was critical to our programmatic success. Although training house staff and fellows is an important institutional mission, in our opinion relying on inexperienced junior physicians to manage complex cases in a new program is not advisable.

In the operating room, a pulmonary transplant attending is present for all cases, as ventilator management, fluid goals, and medications are unique to the lung transplant patient population. Moreover, our presence builds the team mission. It allows the medical team to collaborate with the anesthesia team and identify issues that will be critical in the early postoperative care of the patient. We believe that careful attention to operating room fluids, medication delivery, and early lung-protective ventilation promotes early allograft recovery and decreased hospital length of stay (Fig 3).³³ Once sufficient operating room procedures and experience are in place and center volumes are adequate, it may not be necessary for a pulmonologist to be present.

At our center, postoperative care is performed in collaboration with the cardiothoracic intensivists working closely with the transplant physicians and surgeons. We monitor our ICU days, ventilator days, blood product usage, and laboratory use as measures of quality. Moreover, our patients are followed closely for the first post-transplant year, with weekly visits for the first 3 months

and then monthly visits to complete the first year. We review our 1- and 3-year outcomes quarterly with the multidisciplinary team to provide goal setting and opportunities to discuss quality improvement. This

Figure 2 – IAIV actual and expected lung transplant recipient survival data (2007-2014) compared with national data (US) as reported in the Scientific Registry of Transplant Recipients (SRTR) database. A, One-year recipient survival data. B, Three-year recipient survival data. Number of transplants on the right y axis is number of lung transplant recipients at risk included in the analysis group as depicted by shaded bars. IAIV is Iowa's SRTR center code. See Figure 1 legend for expansion of other abbreviation.

Figure 3 – University of Iowa median length of stay post-lung transplant as reported in SRTR database.³³ See Figure 2 legend for expansion of abbreviation.

approach has resulted in sustained excellence in recipient outcomes, as shown using Kaplan-Meier survival estimates (Fig 4).^{33,34}

Financial Solvency: The revenue stream for a lung transplant program includes the pretransplant evaluation, the actual transplant episode, and posttransplant care. Often times, bundled contracts are such that reimbursement is not based on services provided but rather on a pre-determined fee schedule. As the margin continues to tighten in delivering medical care, it is important to evaluate the usefulness of pretransplant and posttransplant testing and control costs where possible without sacrificing outcomes. Laboratory testing, radiologic imaging, and length of stay dramatically affect the financial

Figure 4 – Kaplan-Meier survival estimates post-lung transplant survival. Kaplan-Meier survival curves comparing the University of Iowa cohort³³ (May 2005 to March 2012) to national recipients of primary lung transplants (extracted from the thoracic Standard Analysis Files, Sept. 2012 version, May 4, 2005 to March 31, 2012³⁴), as reported by the SRTR. Comparisons were made using the log-rank test ($P = .004$). See Figure 2 legend for expansion of abbreviation.

stability of a program; therefore, we review these practices semiannually to make adjustments. We track transplant episode resource use and posttransplant outcomes to identify potential areas for improvement.

CMS approval was critical for the viability of our program. In our case, we were able to perform the requisite number with 100% 1-year survival, and we were inspected and certified 18 months after our first transplant. Of the first 18 transplants, 11 recipients had private insurance and seven had Iowa Medicaid. Therefore, in our case no unreimbursed surgeries were necessary. We use time studies and resource use monitoring to accurately capture pretransplant expenses for the Organ Acquisition Cost Report. This report is an important source of revenue, as organ acquisition charges are the largest fixed expense in transplantation, and a great deal of pretransplant care is otherwise not specifically reimbursable.

Academic Research Mission: The research mission stands equal in importance to the clinical mission of our program. We protect physician time for academic pursuits and evaluate productivity based on publications, clinical trial enrollment, and funding record. To build the research enterprise, our program has a unique leadership of physician scientists. The physicians on our team spend 50% time in research and 50% time on clinical service. This schedule allows our physicians substantial blocks of time for research and also provides respite from the demands of clinical transplant.

The lung transplant program collaborates across the institution on translational and basic science projects that would not exist without access to patients referred to our center and tissues obtained at the time of transplant.³⁵⁻³⁷ In addition, our transplant physicians have active laboratories that study the biology of stem cells in chronic rejection, immune regulation in the lung, and the effect of size mismatch in transplantation.³⁸⁻⁴² This research is supported through intramural and extramural funding sources, including the National Institutes of Health. Thus, our model creates a unique opportunity for synergy between the bench scientists, clinical researchers, and clinicians.

Other Considerations: Since inception, the lung transplant program has been housed within the Heart and Vascular Center at the University. Initially, administrative support was provided by the general hospital compliance office and a 0.5 FTE data manager. As CMS regulations and QAPI requirements have increased dramatically over the past 5 years, as an institution we have moved the

administration of transplant QAPI into our solid organ transplant center.

Conclusions

Strategic analysis of lung transplant program viability should include an assessment of potential transplant volumes and institutional expertise to manage clinical, regulatory, and financial aspects unique to lung transplantation. Programmatic goals should be clearly identified, measured, and reported to team members at regular intervals to ensure quality and durability of the program. At our institution, we use volume, recipient outcomes, financial solvency, and academic research contributions as our identifiable measures.

Acknowledgments

Financial/nonfinancial disclosures: The authors have reported to *CHEST* that no potential conflicts of interest exist with any companies/organizations whose products or services may be discussed in this article.

Role of sponsors: The content is the responsibility of the authors alone and does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the US Government. This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, wait-listed candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN), and has been described elsewhere. The Health Resources and Services Administration (HRSA), US Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors. The data reported here have been supplied by the Minneapolis Medical Research Foundation as the contractor for the SRTR. The interpretation and reporting of these data are the responsibility of the authors and in no way should be seen as an official policy of or interpretation by the SRTR or the US Government.

Other contributions: We thank the University of Iowa Lung Transplant Team, especially Abigail Mack, RN, MNHP; Jana Beaver, RN, BSN; Emily Mathews, LISW CCTSW; Lisa Allen; and Mark Renshaw, MBA, CPHIMS; for data management and Kristin Thiel, PhD, for manuscript review.

References

1. Yusen RD, Christie JD, Edwards LB, et al; International Society for Heart and Lung Transplantation. The Registry of the International Society for Heart and Lung Transplantation: thirtieth adult lung and heart-lung transplant report—2013; focus theme: age. *J Heart Lung Transplant*. 2013;32(10):965-978.
2. Singer JP, Chen J, Blanc PD, Leard LE, Kukreja J, Chen H. A thematic analysis of quality of life in lung transplant: the existing evidence and implications for future directions. *Am J Transplant*. 2013;13(4):839-850.
3. Singer JP, Singer LG. Quality of life in lung transplantation. *Semin Respir Crit Care Med*. 2013;34(3):421-430.
4. OPTN data. Organ Procurement and Transplantation Network website. http://optn.transplant.hrsa.gov/converge/data/request_main.asp. Accessed May 16, 2014.
5. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. *N Engl J Med*. 2003;349(22):2117-2127.
6. Lindenauer PK, Behal R, Murray CK, Nsa W, Houck PM, Bratzler DW. Volume, quality of care, and outcome in pneumonia. *Ann Intern Med*. 2006;144(4):262-269.
7. Turchin A, Shubina M, Pendergrass ML. Relationship of physician volume with process measures and outcomes in diabetes. *Diabetes Care*. 2007;30(6):1442-1447.
8. Transplant laws and regulations. Centers for Medicare & Medicaid Services website. <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Transplant-Laws-and-Regulations.html>. Accessed June 10, 2014.
9. Ornter, NJ. *US Organ and Tissue Transplant Cost Estimates and Discussion*. Milliman Research Report. New York, NY: Milliman Inc; 2005.
10. Orens JB, Estenne M, Arcasoy S, et al; Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation. International guidelines for the selection of lung transplant candidates: 2006 update—a consensus report from the Pulmonary Scientific Council of the International Society for Heart and Lung Transplantation. *J Heart Lung Transplant*. 2006;25(7):745-755.
11. Christie JD, Edwards LB, Kucheryavaya AY, et al. The Registry of the International Society for Heart and Lung Transplantation: Twenty-eighth Adult Lung and Heart-Lung Transplant Report—2011. *J Heart Lung Transplant*. 2011;30(10):1104-1122.
12. Armstrong HF, Schulze PC, Kato TS, Bacchetta M, Thirapatarapong W, Bartels MN. Right ventricular stroke work index as a negative predictor of mortality and initial hospital stay after lung transplantation. *J Heart Lung Transplant*. 2013;32(6):603-608.
13. Shah PD, Orens JB. Guidelines for the selection of lung-transplant candidates. *Curr Opin Organ Transplant*. 2012;17(5):467-473.
14. De Soyza A, Meachery G, Hester KL, et al. Lung transplantation for patients with cystic fibrosis and *Burkholderia cepacia* complex infection: a single-center experience. *J Heart Lung Transplant*. 2010;29(12):1395-1404.
15. Liu V, Zamora MR, Dhillon GS, Weill D. Increasing lung allocation scores predict worsened survival among lung transplant recipients. *Am J Transplant*. 2010;10(4):915-920.
16. Davis SQ, Garrity ER Jr. Organ allocation in lung transplant. *Chest*. 2007;132(5):1646-1651.
17. Egan TM, Murray S, Bustami RT, et al. Development of the new lung allocation system in the United States. *Am J Transplant*. 2006;6(5 pt 2):1212-1227.
18. Policies. Organ Procurement and Transplantation Network website. <http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp>. Accessed June 10, 2014.
19. Eberlein M, Garrity ER, Orens JB. Lung allocation in the United States. *Clin Chest Med*. 2011;32(2):213-222.
20. Hachem RR, Trulock EP. The new lung allocation system and its impact on waitlist characteristics and post-transplant outcomes. *Semin Thorac Cardiovasc Surg*. 2008;20(2):139-142.
21. Klesney-Tait JA, Parekh K. Diamonds in the rough: identification of usable donor lungs. *Am J Respir Crit Care Med*. 2013;188(4):410-412.
22. de Perrot M, Snell GI, Babcock WD, et al. Strategies to optimize the use of currently available lung donors. *J Heart Lung Transplant*. 2004;23(10):1127-1134.
23. Chaney J, Suzuki Y, Cantu E III, van Berkel V. Lung donor selection criteria. *J Thorac Dis*. 2014;6(8):1032-1038.
24. Somers J, Ruttens D, Verleden SE, et al. A decade of extended-criteria lung donors in a single center: was it justified? *Transpl Int*. 2015;28(2):170-179.
25. Pêgo-Fernandes PM, Samano MN, Fiorelli AI, et al. Recommendations for the use of extended criteria donors in lung transplantation. *Transplant Proc*. 2011;43(1):216-219.
26. UNOS bylaws. Designated transplant program criteria. United Network of Organ Sharing website. http://www.unos.org/docs/Appendix_B_AttachI_XIII.pdf. Accessed April 10, 2014.
27. Transplant administrators can now access 2013 staffing survey results. Transplant Pro website. <http://transplantpro.org/2013-unos-staffing-survey-coming-soon/>. Accessed August 2014.
28. Organ Procurement and Transplant Network. Scientific Registry of Transplant Recipients cumulative sum charts: a quality improvement tool for transplant programs [video]. January 8, 2014. Vimeo website. <http://vimeo.com/84304880>. Accessed August 2014.

29. 42 CFR 482.96. Condition of participation: quality assessment and performance improvement (QAPI). US Government Publishing Office website. <http://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-sec482-96/content-detail.html>. Accessed August 2014.
30. Organ Procurement and Transplant Network. *Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR) 2012 Annual Data Report*. Rockville, MD: Department of Health and Human Services, Health Resources and Services Administration; 2014.
31. National OPO-level summary data. Scientific Registry of Transplant Recipients website. <http://srrt.org/opo/Default.aspx>. Accessed October 2006.
32. Klesney-Tait JA, Eberlein M. Lung protective ventilation in donors: an ounce of prevention. *Chest*. 2014;146(1):4-6.
33. US hospitals with lung transplant centers. Scientific Registry of Transplant Recipients website. <http://srrt.org/csr/current/Centers/TransplantCenters.aspx?organcode=LU>. Accessed April 2014.
34. SAF data dictionary – 2014 Q3 external release. Scientific Registry of Transplant Recipients website. http://www.srrt.org/data_request/datadictionary/1409/default.html. Accessed February 7, 2015.
35. Itani OA, Chen JH, Karp PH, et al. Human cystic fibrosis airway epithelia have reduced Cl⁻ conductance but not increased Na⁺ conductance. *Proc Natl Acad Sci U S A*. 2011;108(25):10260-10265.
36. Pezzulo AA, Gutiérrez J, Duschner KS, et al. Glucose depletion in the airway surface liquid is essential for sterility of the airways. *PLoS ONE*. 2011;6(1):e16166.
37. Xie W, Fisher JT, Lynch TJ, et al. CGRP induction in cystic fibrosis airways alters the submucosal gland progenitor cell niche in mice. *J Clin Invest*. 2011;121(8):3144-3158.
38. Sui H, Olivier AK, Klesney-Tait JA, et al. Ferret lung transplant: an orthotopic model of obliterative bronchiolitis. *Am J Transplant*. 2013;13(2):467-473.
39. Klesney-Tait J, Keck K, Li X, et al. Transepithelial migration of neutrophils into the lung requires TREM-1. *J Clin Invest*. 2013;123(1):138-149.
40. Eberlein M, Arnaoutakis GJ, Yarmus L, et al. The effect of lung size mismatch on complications and resource utilization after bilateral lung transplantation. *J Heart Lung Transplant*. 2012;31(5):492-500.
41. Eberlein M, Reed RM, Bolukbas S, et al. Lung size mismatch and survival after single and bilateral lung transplantation. *Ann Thorac Surg*. 2013;96(2):457-463.
42. Eberlein M, Reed RM, Madaa M, et al. Donor-recipient size matching and survival after lung transplantation. A cohort study. *Ann Am Thorac Soc*. 2013;10(5):418-425.