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From Scarcity to Opportunity: Rethinking Lung Donation, Technology, and Access in the U.S. Transplant System

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Lung transplantation remains a critical but constrained treatment option for individuals suffering from end-stage respiratory illnesses, including chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, cystic fibrosis, and pulmonary arterial hypertension. In the United States, while thousands of patients are added to the transplant list annually, the number of lungs suitable for transplantation is severely limited. Many of the donated lungs are ultimately discarded before use, often due to concerns over organ quality or logistical limitations [1]. This issue is further compounded by the narrow criteria used to define "ideal" donor lungs, criteria met by only 10 - 20% of potential donors. These include characteristics such as non-smoking history, normal chest imaging, and adequate oxygenation levels [2,3]. Consequently, a significant proportion of potentially transplantable lungs are excluded from consideration early on, despite evidence suggesting many could function well if reassessed using modern technologies.

A promising innovation addressing this limitation is *ex vivo* lung perfusion (EVLP), a technique that allows for the external evaluation, preservation, and in some cases, rehabilitation of donor lungs prior to transplantation. EVLP creates a controlled, physiological environment in which lungs are ventilated and perfused with an oxygenated, nutrient-rich solution after retrieval and cold storage. Over a 4-12 hour period, the lungs are gradually rewarmed to body temperature and monitored continuously for gas exchange, compliance, pulmonary pressures, and visual condition through imaging and bronchoscopy [4,5]. In addition to standard assessment, certain protocols permit targeted interventions, such as antibiotic administration or anti-inflammatory therapies, further increasing the potential usability of marginal lungs (See figure).

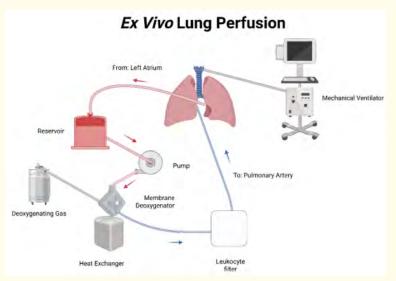


Figure: In the EVLP circuit, perfusate exits the lungs through the left atrial cannula carrying oxygenated fluid, then enters a pump that propels it through the system. It next flows through a membrane deoxygenator, which removes oxygen and adds carbon dioxide to mimic venous blood. The perfusate then passes through a leukocyte filter to remove inflammatory cells and debris before being returned to the pulmonary artery. This closed-loop circulation replicates physiologic conditions, allowing continuous assessment of lung function outside the body. Created in BioRender. Jenks, C. (2025) https://BioRender.com/yn4drq5.

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Clinical evidence, including results from the INSPIRE trial, indicates that lungs evaluated and reconditioned through EVLP produce post-transplant outcomes comparable to those from standard-criteria donors. Studies show no significant differences in primary graft dysfunction, hospital length of stay, or mortality [5]. Real-world data and meta-analyses have confirmed EVLP's effectiveness in expanding the pool of usable donor lungs, particularly by enabling the safe use of extended criteria donors (ECDs) those with characteristics like advanced age, prior smoking, suboptimal PaO₂ levels, or infection history [4,6].

Several EVLP systems are now utilized in clinical practice. The Toronto Protocol, pioneered by Cypel and colleagues, established foundational methods for EVLP lung reconditioning [4]. Commercially available systems include the XVIVO Perfusion System, popular in Europe and North America, and the Organ Care System developed by TransMedics, which provides a portable platform for lung transport and evaluation. Despite these advancements, EVLP remains underutilized in the U.S., largely due to infrastructure and financial barriers. Many smaller transplant centers lack the necessary equipment, trained personnel, or consistent reimbursement mechanisms to implement EVLP [6]. Expanded use could be facilitated through the development of regional EVLP hubs, increased insurance support, and targeted workforce training.

Simultaneously, the transplant field is reassessing the definition of acceptable donor lungs. Growing research supports the use of lungs from donors previously considered high-risk, such as those with controlled infections, extended intubation periods, or smoking histories [3]. These findings are shifting donor acceptance paradigms based on clinical outcomes rather than rigid criteria. At the systems level, inefficiencies in organ procurement remain a significant challenge. Between 2020 and 2022, only 10 of the 44 largest Organ Procurement Organizations (OPOs) in the U.S. maintained lung allocation rates above 25% [6]. The U.S. transplant system, comprising more than 50 regionally independent OPOs, suffers from inconsistencies in donor management, logistical execution, and overall performance. The National Academies of Sciences has highlighted this variation, noting that some OPOs retrieve lungs from fewer than 10% of eligible donors, while others achieve recovery rates exceeding 30% [7]. Enhancing regulatory oversight and promoting best-practice sharing may reduce disparities and improve nationwide outcomes.

Public awareness and consent practices significantly influence lung donation rates. The U.S. operates under an opt-in model, requiring individuals to register as organ donors. Despite millions of Americans being registered, many donor opportunities are lost due to family refusals, ambiguous documentation, or mistrust in the healthcare system [8]. Educational initiatives have proven effective in increasing registration and consent rates, particularly when tailored to underrepresented communities.

Additionally, reforms in lung allocation policies are underway. The shift from a geographic, zone-based model to a continuous distribution system now incorporates a range of factors, such as medical urgency, proximity, post-transplant survival probability, and blood type, into a composite score to guide allocation. This aims to create a more equitable and efficient distribution system, particularly benefiting patients in remote or underserved areas. However, operational challenges, including transportation delays and limited logistics support, continue to hinder progress, emphasizing the need for infrastructure investment like dedicated transport systems and real-time tracking technologies.

Ethical considerations remain paramount as innovations and policy reforms reshape lung transplantation. It is essential that transplant teams maintain robust informed consent protocols, particularly when utilizing extended-criteria or *ex vivo* reconditioned donor lungs. These discussions must clearly communicate the associated risks and the origins of the donated organs to ensure that recipients make fully informed decisions. At the same time, disparities in access to lung transplantation continue to raise concern. Studies have shown that patients from racial and ethnic minority groups often face structural and systemic barriers that contribute to lower transplant rates and prolonged wait times [9-11]. Although most available data on this issue stem from broader organ transplantation contexts, similar trends have been observed in lung transplant programs. Tackling these inequities demands a multifaceted approach - one that includes enhancing equity in patient referral practices, improving access to insurance and financial support, and promoting diversity within transplant leadership and oversight structures.

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While future innovations such as bioengineered organs and xenotransplantation hold great promise, they remain largely experimental. The immediate opportunity to save lives lies in optimizing existing resources, particularly by fully leveraging EVLP, broadening donor eligibility, and standardizing OPO performance. In this context, every viable lung matters. Enhancing organ donation and transplantation processes in the U.S. is not only a technical necessity but also a pressing public health obligation.

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