



September 28, 2022

Keren Ladin, MD
Chair, Ethics Committee
Organ Procurement and Transplantation Network
United Network for Organ Sharing
700 N 4th St
Richmond, VA 23219

RE: Transparency in Program Selection

Submitted electronically at <http://optn.transplant.hrsa.gov>

Dear Dr. Ladin:

On behalf of the Cystic Fibrosis Foundation (CFF) and the below signed individuals of the CF Lung Transplant Consortium, we write in response to the Organ Procurement and Transplantation Network (OPTN) / United Network for Organ Sharing Public Comment on *Transparency in Program Selection*.

Background on Cystic Fibrosis and the CF Foundation

Cystic fibrosis (CF) is a rare genetic disease that affects nearly 40,000 people in the United States. In people with CF, defects in the CFTR gene result in a buildup of thick mucus in multiple organ systems, including the lungs and pancreas. In the lungs, mucus obstructs the airways and traps bacteria, leading to infections, extensive lung damage, and eventual respiratory failure. Historically, over 200 individuals with CF have received an organ transplant each year with CF; this accounts for approximately 10-15% of the annual lung transplant volume. Although lung transplants have declined dramatically since 2019 due to the development of highly effective modulator therapies, many individuals with CF will continue to require lung transplantation. Some people with CF will also develop liver or kidney failure and require transplantation of those organs. Additionally, combined kidney-pancreas transplant occasionally occurs as pancreatic exocrine insufficiency and CF-related diabetes are common in this population.

To address the needs of people with CF living with advanced lung disease, including those considering transplant, the CF Foundation launched the Lung Transplant Initiative in 2016. Through this initiative, the Foundation is working to improve and standardize care for people with CF for whom transplant is an option. We therefore appreciate the OPTN Ethics Committee's commitment to patient-centered and program-specific transparency. Based on the mission of our organization and the needs of our community, we offer the following comments.

Importance of Transparency

We strongly support the Committee's commitment to increasing patient access to information about transplant program criteria, evaluation processes, and wait listing decisions. Providing patient, family, and provider friendly literature that refers to broad inclusion and exclusion for a particular transplant

facility will help ensure patients make informed, timely decisions as to which transplant program is best suited to meet their individual needs and circumstances. Patients should be provided this information at the time of referral and prior to initial transplant consultation, if feasible, to aid in program selection and avoid unnecessary expenditure of travel and time. Transparency in program selection could increase timely access to the transplant and allow patients to be seen more expeditiously at programs where they have the best potential for waitlist acceptance if relative or absolute contraindications are present.

Recommendations for Program Selection Transparent Criteria

We recommend OPTN develop a standardized, national template for all transplant centers to use as a way to ensure the literature is accessible and patient, family, and provider friendly. This information should be available on the OPTN website, similar to the transplant program data available on the Scientific Registry of Transplant Recipients (SRTR) website. The SRTR website allows individuals to find, view, and compare data from transplant programs by type of organ. In order to make the right choice when evaluating which transplant program is the best match, patients need to be able to understand the criteria, discuss with their care team, and compare programs to ensure they are referred to a center that meets their needs. While we are aware transplant programs fluctuate based on practices, clinicians, preference, and other factors, providing a baseline for patients to work from can ease the process when determining which transplant center may be the best fit.

Some criteria we recommend including in a standardized template refer to the patient's profile, including (but not limited to): infection status, BMI and nutritional status, narcotic use or dependence, cannabis use (medical or recreational), tobacco use, renal function and dialysis status, history of cardiac and prior thoracic surgery (pleurodesis or re-do transplant), as well as potential need for dual organ transplantation. Of course, candidate waitlist decisions encompass additional factors beyond health status. Other criteria include requirements for relocation, pulmonary rehabilitation, financial and insurance coverage (including in-network and out-of-network status), and social support. This is not an exhaustive list and we recognize some of the above listed criteria are modifiable candidacy issues. The transplant centers should be clear which criteria are absolute and which are relative and potentially modifiable with time and assistance. This would allow candidates to begin trying to optimize their candidacy immediately and arrive at the transplant center knowledgeable and potentially with a plan of action.

We understand not all transplant centers are comfortable sharing information prospectively as programs fluctuate and evolve, but general guidelines and trends could be provided with an available pathway to contact the center for a brief discussion of individual circumstances. Currently, referring providers can, and often do, contact transplant center staff to discuss candidacy questions and policies, but patients and families generally cannot. At minimum, transplant centers should be required to provide a publicly available dashboard with numbers of transplant by diagnosis and the transplant criteria listed above. While potentially not as informative or comprehensive, retrospective data at least provides patients, families, and providers the opportunity to view trends in an accessible format when reviewing transplant centers. One approach would be to ask each organ transplant committee at UNOS to discuss which candidacy factors should be included in the request for information from each program. Attention to diversity in educational background, health literacy, culture, and language is critical in any public facing information to maximize understanding and thus transparency for potential candidates and their families. To that end, it may be beneficial to engage focus groups of underrepresented minorities to provide feedback on sample language, accurate translations, and cultural considerations.

Stakeholder Engagement

We believe candidate and provider engagement is essential for a successful, streamlined process. Timely referral may be improved if candidates and providers have a mechanism to engage with the transplant facility prior to referral. We understand that every case is handled on an individual basis and if a center is willing to accept the referral and look at medical records, that does not automatically mean they will agree to evaluate and list someone. This is why ensuring potential candidates have a way of engaging with the transplant center prior to evaluation is so crucial.

Finally, health insurance coverage limitations remain a barrier to patients accessing the transplant program that may best fit their needs. OPTN should work with the Department of Health and Human Services to reduce this burden and make it easier for patients to access the appropriate transplant center.

Conclusion

As strong proponents of shared decision making and patient autonomy, we fully support increased transparency in candidate selection criteria to guide transplant center selection. When transplantation is being contemplated and resources and time are invariably limited, the ability for a patient and their family to navigate their way to the program that is most likely to meet their individual needs and circumstances is critically important and has ultimately may make the difference between life and death.

We thank the OPTN Ethics Committee for this opportunity to provide feedback on the *Transparency in Program Selection* white paper. We are happy to serve as a resource and look forward to working alongside OPTN in the future on this issue.

Sincerely,



Albert Faro, MD

Vice President, Clinical Affairs
Cystic Fibrosis Foundation

CF Lung Transplant Consortium Members

A. Whitney Brown, MD

Senior Director, Clinical Affairs
Cystic Fibrosis Foundation

Gundeep Dhillon, MD, MPH

Medical Director, Heart-Lung & Lung Transplantation Program
Stanford HealthCare

Ramsey Hachem, MD

Professor of Medicine, Lung Transplant Program Medical Director
Washington University School of Medicine

Matthew Hartwig, MD, MHS

Associate Professor of Surgery
Program Director, Minimally Invasive Thoracic Surgery Fellowship
Division of Thoracic Surgery
Duke University Health System

Jagadish Patil, MD

Assistant Professor of Medicine
Division of Pulmonary, Allergy, Critical Care, and Sleep Medicine
University of Minnesota

Joe Pilewski, MD

Associate Chief, Division of Pulmonary, Allergy & Critical Care Medicine
University of Pittsburgh Medical Center

Kathleen Ramos, MD, MSc

Assistant Professor of Pulmonary, Critical Care, and Sleep Medicine
University of Washington, Seattle

Stuart Sweet, MD, PhD

Professor of Pediatrics, Division of Allergy, Immunology and Pulmonary Medicine
Medical Director, Pediatric Lung Transplant Program
Washington University School of Medicine in St. Louis

Erin Tallarico, RN, BSN

Clinical Director, Advanced Lung Disease Program
Cystic Fibrosis Foundation

Fanny Vlahos

Cystic Fibrosis Lung Transplant Consortium Patient Representative

Stephen Weigt, MD

Associate Professor of Medicine, Pulmonary and Critical Care
UCLA Medical Center