



Cystic Fibrosis Foundation

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Title: Organ Procurement and Transplantation Network (OPTN)

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May 9th, 2022

Administrator Carole Johnson
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857 U.S.A.

Re: Request for Information; Organ Procurement and Transplantation Network

Dear Administrator Johnson:

The Cystic Fibrosis Foundation writes in response to the Health Resources and Services Administration's (HRSA) request for information on *Ways to Strengthen and Improve the Organ Procurement and Transplantation Network*. We thank HRSA for the opportunity to provide feedback on potential changes and improvements to the Organ Procurement and Transplantation Network (OPTN).

Background on Cystic Fibrosis and the CF Foundation

Cystic fibrosis (CF) is a rare genetic disease that affects over 30,000 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 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 HRSA's recent request for information regarding ways to strengthen and improve the OPTN. In particular, we view this comment opportunity and the upcoming renewal of the OPTN contract as an opportunity to refocus the transplant process around patients and their experiences. Based on the mission of our organization and the needs of our community, we offer the following comments.

Data Collection Activities (Sec. B.1, Sec. B.2.a - B.2.e)

One of the first steps to creating an equitable organ procurement and transplant system is expanding data collection to include disaggregated demographic information such as race, ethnicity, gender, language, and socioeconomic factors. We appreciate HRSA's commitment to doing so and recommend including quality of life metrics when tracking health and non-health metrics along with long-term health outcomes. Data collection should encompass donors, recipients, and potential transplant candidates; to the extent possible, the OPTN should attempt to backfill this information on previous donors, recipients, and potential transplant candidates when setting up their enhanced data collection parameters.

Throughout these efforts it is critical that the OPTN keep in mind its obligations to vulnerable and underrepresented populations. We share and support the OPTN's goal of strengthening equity and access in the organ donation, allocation, procurement, and transplantation process. Data from the CF patient registry (which includes data on race/ethnicity, marital status, education level, employment, insurance type, zip code, and distance to transplant centers) indicate that patients with greater socioeconomic barriers access transplant half as often as those with fewer barriers, regardless of disease severity. Because disparities in the process frequently occur prior to the time of listing, collecting these data at time of referral would be valuable for characterizing and addressing referral bias. Though logistically challenging, these efforts could begin in collaboration with patient advocacy groups, particularly those with registries, such as the CF Foundation, the Pulmonary Hypertension Association, and the Pulmonary Fibrosis Foundation.

We encourage the development of a standardized set of metrics regarding access and performance of transplant centers and organ procurement organizations (OPOs), as well as the creation of a publicly available dashboard to track those metrics across the organ procurement and transplant system. Data elements included should be chosen in consultation with donor patients and families, individuals with chronic disease, transplant candidates and recipients as well as their families to ensure that the information provided is relevant and patient centered. It should be incumbent upon the OPTN to reach out to these community stakeholders and actively solicit feedback regarding these metrics.

Organ Usage (Sec. F.1-F.3)

Organ non-usage represents an unnecessary failure of the transplant system, and measures to decrease discard and increase usage of organs may be implemented at multiple stages of the procurement and transplant process. Procured organ discard can be decreased by working with transplant centers to develop standardized, evidence-based criteria for organ quality assessment by OPOs prior to organ allocation, thereby mitigating non-usage due to discrepancies in standards between transplant centers and OPOs. Increased utilization of local or regional procurement teams by transplant centers may facilitate more rapid procurement of organs without taking surgeons away from planned procedures. These efforts may further be aided by the establishment of donor care units managed by OPOs or housed within transplant hospitals which may result in more control and optimization of donor management and procurement

timing. Lastly, we support standardization of protocols related to donation after circulatory death through such channels as the OPTN's collaborative OPO DCD procurement project. Continued effort in this domain is crucial to reduce variability in practice and increase organ utilization around the country.

To better prepare themselves to accept offered donor organs whenever they become available, hospitals with transplant centers should be required to prioritize transplant surgical scheduling and maintain the capacity to open an operating room expeditiously in case of a transplant procedure.

Given the disincentives for transplant centers to accept medically complex organs or recipients, the OPTN should additionally consider developing a risk stratification system for performance metrics. Establishing such a system with performance metrics for standard and medically complex allografts and recipients would help prevent hospitals that accept such cases from being "penalized" for doing so. Utilization of organs with marginal or less optimal quality and transplantation of medically complex recipients may be further improved through sharing of "best practices" from groups that perform such procedures. Standard criteria for each of these categories would need to be developed to remove subjectivity and avoid overuse.

To implement meaningful change, the OPTN will need to innovate with courage. We are not advocating for an approach that encourages undue risk taking and results in poor outcomes for patients; rather, we recommend the adoption and promotion of a calculated risk framework for organ transplant using a quality improvement approach that allows for learning and advancement. For example, some patients with cystic fibrosis are chronically infected with organisms known to be associated with poorer post-transplant outcomes. A system in which a few select centers with expertise in clinical care and quality improvement methodology are equipped to transplant these high-risk individuals would prevent these patients from being denied a lifesaving transplant. These centers would not be penalized for below average one-year outcomes; instead, they would be given the opportunity to learn and improve their approach to these high-risk patients. Indeed, the OPTN has already piloted this type of approach with the COIIN project (<https://unos.org/news/improvement/what-we-learned-coiin/>), which is intended to leverage transplant center and OPO partnerships to increase the use of higher-risk kidneys. We further emphasize a focus on intermediate and long-term outcomes (three- and five-year survival), rather than one-year survival, given that some individuals with below-average one-year survival have comparable three- and five-year survival to average-risk lung candidates.

We appreciate HRSA's investment in improving transparency of the organ matching and acceptance process for patients and other stakeholders. To bolster accountability, transplant centers should be required to keep patients on the transplant waiting list informed of the number of, and justification for, declined organ offers for themselves as individuals. Accurate identification of the reasons for organ declinations and barriers to organ acceptance will necessitate increased granularity of refusal codes and reduced risk of penalization for use of particular refusal codes. The OPTN should further be required to investigate methods to promote effective communication between patients and transplant teams during the organ offer process.

This process will be naturally facilitated by thorough patient education during the evaluation and listing period, as discussed below.

Stakeholder Engagement (Sec. H.1-H.3)

We believe that federal oversight and stakeholder engagement should begin earlier than the time of listing. Having a process in place that includes steps to ensure patients are being identified as potentially needing a transplant and subsequently referred for evaluation should be considered; timely referral may be improved through educational and patient awareness programs targeted at commonly transplanted patient groups. Importantly, these educational efforts should address the referral bias described above by highlighting existing disparities and working with stakeholders to increase referral rates among marginalized populations.

The OPTN should also develop standardized, streamlined educational materials (printed and online) regarding patient rights, as well as information on the transplant process and system, including the OPTN and OPOs. Ideally, patients should be provided this information at time of referral or initiation of transplant evaluation, depending on feasibility. These tools may be paired with improved OPTN website navigability and increased solicitation of patient engagement, including both candidates and recipients, as well as donor families. Efforts to improve the patient experience from the outset of the transplant process would be bolstered by the establishment of an optional peer mentorship program to provide guidance to those entering the system. The entirety of this program, including mentor training, database maintenance, and peer matching, should either be run through the OPTN or subcontracted out to other entities to avoid transplant center bias.

Quality Improvement

We believe that enhanced quality improvement programming is one of the most important considerations for the OPTN contract renewal. Continuous quality improvement must be embedded through the transplant system—including OPOs and donor hospitals, not just transplant centers—to improve and reduce variations within the transplant process. These efforts should begin with identification of potential transplant candidates and continue through post-transplant care and should align with the performance metrics described above. We stress that patient and community voices must be included in this process and that stakeholder representation should be required during program creation, evaluation, and policymaking.

In addition to existing collaborative improvement projects, we recommended the establishment of regional quality improvement collaboratives and networks to promote dissemination of best practices and lessons learned, with the goal of creating high value, high performing transplant processes and systems, improving relationships between all entities involved in the transplant process, and ensuring exceptional care for transplant patients and their families. Other than the Individual Member Focused Improvement pilot initiative, there are currently few resources for developing and adhering to best practices for processes such as creation of patient family advisory boards and provision of quality improvement team education. The OPTN should develop and require participation in training and peer mentorship programs for each stakeholder in the process, including donor hospitals, OPOs, and transplant centers. Critical to quality

improvement is the systematic sharing of best practices, both by OPTN and other nexuses of the transplant process, including OPOs and transplant centers. This will require active cultivation of a collaborative model of information sharing and the development of a platform through which entities are able to do so easily.

We thank HRSA for this opportunity to provide feedback on this request for information regarding *Ways to Strengthen and Improve the Organ Procurement and Transplantation Network*. We are happy to serve as a resource and look forward to working alongside HRSA in the future on this matter.

Sincerely,

Albert Faro, M.D.

Handwritten signature of Albert Faro in black ink.

Vice President, Clinical Affairs
Cystic Fibrosis Foundation

Mary Dwight

Handwritten signature of Mary Dwight in black ink.

Chief Policy and Advocacy Officer
Cystic Fibrosis Foundation