

Request for Information (RFI): Strategies to Improve Outcomes and Transform Heart Transplantation

1. Introduction

As part of a comprehensive research analysis, we now invite qualified investigators from a broad list of scientific domains, individuals with lived experience, institutions, or pharmaceutical/device entities to provide insights into the critical areas of heart transplantation that must be transformed to significantly improve outcomes for these patients.

This Request for Information (RFI) seeks to gather information that could inform innovative approaches to improve patient outcomes such as enhanced interventions, including clinical trials, policies, or novel data analyses.

2. Background

Heart transplantation is the gold standard for treating end-stage heart failure in pediatric and adult patients. The last decade has seen significant increases in the number of heart transplants, and survival rates continue to improve. Nevertheless, persistent challenges and gaps limit the availability of donor hearts and the long-term survival of patients who have undergone heart transplantation, as well as the achievement of optimal patient outcomes and experience.

The path to transplant surgery, recovery and long-term survival has multiple stages and is multi-faceted.

- A. Pre-transplantation
 - a. Heart failure assessment, monitoring, and therapies
 - b. Formal listing for transplant
 - i. Health care financing
 - ii. Donor organ allocation policies
 - c. Donor organ procurement
 - i. HLA matching
 - ii. Desensitization techniques
 - iii. Improving immune tolerance
 - iv. Donor organ preservation
 - v. Organ fabrication
- B. Operative period (24 hours)
 - a. Assessment of donor organ suitability
 - b. Timing and choice of immunosuppressives
 - c. Concomitant surgery, pacemakers, etc.
- C. Long term strategies
 - a. Immunosuppression

- b. Surveillance for and treatment of rejection
- c. Surveillance for and treatment of coronary vasculopathy
- d. Other complications:
 - i. Kidney disease, diabetes mellitus, obesity, hypertension, malignancy

3. Key Questions

1. What fundamental problem(s) exist today that if addressed will transform clinical heart transplantation and improve patient outcomes?
2. What innovative strategies would you suggest addressing the above fundamental problem(s)?
 - a. Responses should ideally address both children and adults needing a heart transplant.
 - b. Responses should ideally address patients with all forms of end-stage heart failure, including congenital heart disease.
 - c. Responses could include but are not limited to immunological interventions, bioengineering or preservation of donor organs, novel rejection management strategies, policy changes or surgical approaches.

4. Examples of respondents to this request for information

- Respondents should have a demonstrated track record in end-stage heart failure therapies, transplant immunology, immunosuppressive and immunomodulatory therapies, transplant surgery, or cardiovascular or bioengineering research. Patients who have undergone heart transplant or their families are encouraged to respond. Scientists outside the field of heart transplant are welcome to provide a response in their area of expertise.
- Collaborative responses that bring together experts from diverse fields (e.g., immunology, pharmacology, genetics) are encouraged.
- Institutions with access to clinical populations of heart transplant recipients are especially encouraged to respond.

5. Submission Guidelines

- Responses are limited to a maximum of 500 words per fundamental strategy.
- Responses must be submitted electronically by March 25, 2025 via this [JotForm link](#).
- All submissions should be formatted as a single PDF document.

6. Timeline

- RFI Release Date: Monday, February 3, 2025
- Information Submission Deadline: Tuesday, March 25, 2025

For questions or further information regarding this RFI, please email rfi@heart.org.



ADDITIONAL
VENTURES

We look forward to receiving valuable information to advance the field of heart transplantation and improve outcomes for patients. Your expertise and dedication are vital to addressing the ongoing challenges in heart transplantation.