

OPTN Modernization Discovery Task Summary

HRSA Organ Transplant Innovation

Introduction

HRSA is leading a historic modernization of the Organ Procurement and Transplantation Network (OPTN), designed to improve transparency, performance, governance, and efficiency. As part of this effort, HRSA engaged an independent contractor, MITRE, to assess how organ allocation policies could be more consistently and transparently evaluated, strengthening oversight of the Organ Procurement and Transplantation Network (OPTN). MITRE's Health Federally Funded Research and Development Center (Health FFRDC) goals for this discover task included:

- Developing a comprehensive evaluation framework to assess organ allocation policies
- Engaging the community to ensure the framework reflects system realities
- Identifying methods, measures, and data sources to support evidence-based evaluation

Disclaimer

This document summarizes the findings and recommendations of the contractor. It is provided for informational and transparency purposes only and does not represent the official policy or endorsement of the U.S. Department of Health and Human Services (HHS) or the Health Resources and Services Administration (HRSA). All final decisions regarding solicitations, requirements, and implementation rest solely with the U.S. Government. Additionally, HRSA will ensure that the OPTN, through close collaboration with the Board of Directors and other stakeholders, advises, reviews, and provides necessary input to enable HRSA to match vendor services to the needs of the OPTN.

Contractor's Current-State Findings

MITRE's detailed evaluation questions and measurable indicators in existing OPTN and CMS data with new qualitative insights would reduce burden while improving analytic depth as observed in repeatable methods to evaluate OPTN policies along three dimensions:

1. Policy Content

- Defines what a policy seeks to change, why it was created, and how it aligns with prior policy

- Examines the clarity of implementation guidance, resource needs, and monitoring plans
- Uses qualitative text analysis and simple quantitative measures to assess clarity and completeness

2. Policy Implementation

- Explores how policies are communicated, adopted, and monitored by OPTN members
- Identifies variation in compliance and the operational realities affecting policy uptake
- Recommends combining document review, stakeholder interviews, and OPTN data to assess compliance indicators such as AOOS events, offer acceptance timing, and staff training

3. Policy Impact

- Evaluates effects on patient outcomes, system operations, and financial implications
- Measures outcomes across the full transplant pathway, from referral to post-transplant survival
- Encourages risk-adjusted, comparative, and stratified analyses to detect both intended and unintended effects

Contractor's Future-State Recommendations

MITRE identified key themes when expanding analytic guidance, adding new measures (e.g., cold ischemic time, offer acceptance timing), and emphasizing early and long-term evaluation phases. Key themes included:

- Cross-System Evaluation: Policies must be assessed not only for clinical outcomes but also for how implementation varies by organization type, size, and resources
- Qualitative Insight: Quantitative data alone cannot capture operational challenges or human factors
- Transparency: Dissemination of findings and clear communication to patients, referring physicians, and the public are essential to trust
- Operational Realism: Time, workforce, and data collection burden should be explicitly considered in policy rollout and evaluation

Considerations

Cross-Cutting Recommendations

MITRE identifies several modernization needs:

- Collaborate early to include clinicians, OPOs, and patients in designing both policies and evaluations
- Leverage existing data to integrate OPTN and CMS datasets, prioritize interoperability, and limit redundant reporting
- Plan evaluations proactively to design evaluation protocols concurrently with policy development to identify metrics, baselines, and pilot studies
- Improve communication to develop plain-language materials, tailored training, and transparent public reporting
- Support system learning to use evaluations not only to monitor compliance but to guide improvement and innovation

Conclusion

The discovery tasks culminated in a comprehensive and stakeholder-informed Evaluation Framework that strengthens the foundation for evidence-based policy assessment across the U.S. organ allocation system. HHS is publishing these materials to promote transparency and to support a competitive, informed procurement process that advances fairness, accountability, and performance in organ transplantation.