

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 examine organ transportation logistics and develop recommendations for standards, technologies, and data systems to enhance transparency and performance, supporting the broader OPTN Modernization initiative to improve fairness, safety, and oversight of the U.S. organ procurement and transplantation system. MITRE's Health Federally Funded Research and Development Center (Health FFRDC) analyzed existing technologies, operational standards, and user requirements through research and stakeholder engagement, not government policy.

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 observed organ logistical failures stemming from preventable breakdowns—lost tracking visibility, temperature excursions, or communication gaps—rather than unavoidable events and several viable technologies applicable to organ transport in standardized data plus flexible technology adoption—allowing innovation while ensuring reliability and accountability.

Common logistical themes included:

- Inconsistent location and temperature tracking during transport
- Limited communication standards across OPOs, transplant centers, and couriers
- Minimal national data reporting requirements for logistics performance
- Lack of centralized visibility into in-transit organ status or root-cause data on losses

Technology and data landscape themes included:

- Tracking technologies such as optical scanning (barcodes), RFID, Bluetooth Low Energy (BLE), and GPS devices, all varying in cost, precision, and power needs
- Condition monitoring such as temperature indicators, data loggers, and real-time sensors with cloud connectivity
- Data exchange tools in APIs and open standards such as HL7 FHIR and ISBT-128 for data interoperability
- Centralized visibility systems (real-time transportation visibility platforms or RTTVPs): Platforms like Project44 and Pulse Charter Connect that integrate tracking data and alerts

Contractor's Future-State Recommendations

MITRE identified three future-state recommendations to support organ transportation logistics:

1. Foundational operational standards to reduce logistics-related nonuse of organs:

- Location tracking for every organ shipment requiring the use of a GPS-enabled device to transmit and store location data throughout transport
- Temperature monitoring as organ temperature must be measured during transport using a calibrated device meeting national standard
- Critical communication, including a documented communication log must be maintained among all entities in the logistics chain to record itineraries, delays, and temperature alerts

2. Future logistics system design of a centralized organ logistics visibility system integrated with existing OPTN technology to:

- Aggregate data from tracking devices and couriers
- Enable analytics and alerts
- Provide oversight bodies with tools for root-cause analysis

3. Emerging Technologies for future-facing options:

- Drones and advanced air mobility
- Organ perfusion devices for real-time viability monitoring
- Biosensors capable of detecting organ stress

Considerations

Cross-Cutting Recommendations

MITRE identifies several modernization needs:

- Review and validate operational standards with OPTN members for feasibility
 - Align logistics data standards with forthcoming organ data directives
 - Develop a phased implementation plan, starting with pilot projects
 - Create training and SOP templates for OPOs and couriers
- Establish oversight protocols to ensure consistency and reduce administrative burden

Conclusion

By establishing operational standards, leveraging real-time tracking technology, and integrating centralized data systems, HHS can improve accountability, reduce avoidable losses, and enhance organ transportation safety nationwide. The discovery findings provide a technical foundation for modernization and for collaborative improvement across the transplant community.