

Final Organ Transplant Logistics Tracking Technology Options and Support Services Overview

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Executive Summary

Introduction and Current Challenges

The 1984 National Organ Transplant Act (NOTA) requires the Health Resources and Services Administration (HRSA) to oversee the Organ Procurement and Transplantation Network (OPTN), which is responsible for allocating and distributing donor organs to individuals waiting for transplants. The procurement and transplantation of organs requires transport of organs from virtually any location in the country to over 250 transplant centers nationwide. The physical movement of organs relies on a complex network of organizations and individuals, including transplant centers and surgeons, organ procurement organizations (OPO), commercial airlines, couriers, and other organizations supporting end-to-end organ transplant logistics. Reports of organs being damaged, lost, delayed, or rendered unusable due to transportation issues have increasingly raised concerns about the current state of the nation's organ tracking system. In March 2023, the Department of Health and Human Services (HHS) launched an OPTN modernization initiative to improve patient outcomes by improving reliability, transparency, and performance of organ transplant logistics that minimizes organ nonuse and maximizes transplantation rates.

Objectives and Approach

In 2024, HHS asked MITRE, operator of the Health Federally Funded Research and Development Center (FFRDC), to identify current and emerging logistics tracking technologies, data standards, and systems used by private industry, the organ transplantation ecosystem, and the federal government. The Health FFRDC conducted a scan of available literature and interviewed organ transplant, industry, and government logistics organizations. This research will inform the development of requirements that will provide the transplant community with clear and transparent information on organ tracking logistics to improve success rates of organ use.

Logistics Technologies

Stakeholders in the organ transplant logistics ecosystem face an increasingly complicated challenge of trying to ensure organs are quickly and transparently moved from one location to another, while preserving the vitality of the organ. There are three aspects of technology that are essential to consider when modernizing the organ logistics ecosystem: 1) in-transit tracking technologies; 2) data standards and application programming interfaces (APIs) for data-sharing interoperability; 3) centralized system like a real-time transportation visibility platform (RTTVP).

Location Tracking

In the logistics industry, companies use tracking technologies (e.g., optical scanning, radio frequency identification, Bluetooth low-energy, and global positioning services devices) to monitor and collect information on the location and condition of shipments. These tracking technologies range in cost and capabilities. Based on interviews with organ transplant logistics organizations, OPOs and logistics couriers use varied tracking technologies and require flexibility to select the tracking technology best suited for their environment and specific needs. Single-use trackers are important in organ transplant logistics to reduce cost and waste.



Temperature and Condition Tracking

Several organizations discussed the need for temperature monitoring for informed decision-making and trust in the condition of the organ by the receiving transplant center. Across industries, three types of temperature trackers are used: 1) single use temperature indicators, 2) data loggers, and 3) real-time monitoring devices. Single use temperature indicators are the most basic and cost-effective while real-time temperature monitoring devices are more expensive but can provide continuous temperature monitoring and transmit data if packages exceed temperature thresholds.

Data Standards and Exchange

HHS and organ transplant logistics stakeholders need standardized data from when the organ is matched throughout transportation to the organ's final disposition. The logistics industry has minimal data standards, and adoption and implementation vary widely. APIs are often used to integrate real-time tracking information from various sources to a centralized platform. For organ transportation, APIs can facilitate sending organ tracking to a centralized platform or potentially trigger alerts for when temperatures go out of range. ^{2,3}

RTTVP

RTTVP and centralized control towers could be foundational to providing visibility into the organ transplant logistics ecosystem. RTTVPs are a single interface with a comprehensive, dynamic view of shipments. RTTVP capabilities enable users to plan for cost and time for transport, track real time location, communicate across stakeholders, and analyze trends and predict future outcomes.⁴ Centralized supply chain control towers include trained experts, standardized processes, and monitors the RTTVP in real time, similar to air traffic control.⁵ Companies with these capabilities often use artificial intelligence (AI) and machine learning (ML) to enhance their real-time status monitoring and issue resolution (e.g., predicting disruptions and re-routing).

Emerging Technologies

Integrating emerging technologies has the potential to transform organ transport by shortening transport times or lengthening the time that an organ can remain viable. These technologies include advanced air mobility (AAM),⁶ organ perfusion technologies,⁷ and biosensors – "Organs-on-Chips." Biosensors are particularly promising with their ability to: 1) monitor the levels of oxygen, glucose, and other vital metabolites in the preservation solution; 2) detect signs of organ damage or rejection; and 3) provide real-time feedback on the organ's viability.⁸

Discussion and Next Steps

HHS can address many of the organ transplant logistics challenges with existing technology. The Health FFRDC will continue this work and conduct interviews with OPOs, transplant centers, and logistics couriers to further analyze logistics capabilities and identify additional challenges. Once complete, the Health FFRDC will develop business requirements HHS can use to improve the transparency and outcomes related to organ transportation.

The recommended business requirements will include:



 Minimum OPTN requirements for OPOs, logistics providers, and transplant centers for using organ tracking technologies and data collection and reporting

To determine the minimum tracking technology HHS should direct the OPTN to require along with the minimum data to collect and share, consideration must be given to the cost of real-time monitoring devices, OPTN transportation-related policies, and the system user needs for access to real-time data. In the near term, HHS efforts should focus on identifying important data elements that OPTN data collection should include, and determining how, when, and to whom to track and report data.

2) HHS requirements for a centralized organ transplant logistics visibility system for data capture, storage, analysis, and information sharing

As partners increasingly use tracking technology and HHS collects relevant data, HHS will need a system to collect, share, and analyze data for process and system improvement. This type of system will increase transparency, which stakeholders and the public have wanted for a long time, and in turn provide more accountability for each entity's performance. A centralized organ transplant logistics visibility system will also enable timely identification of challenges, root cause analysis for adverse events, and improved patient outcomes.



Introduction

Across the U.S., over 100,000 individuals are on the organ transplantation waiting list with an average of 17 people dying each day waiting for an organ. The procurement and transplantation of organs requires the identification of potential organ donors, the matching of organs with potential recipients, and the transport of organs from virtually any location in the country to over 250 transplant centers nationwide. The physical movement of organs relies on a complex network of organizations and individuals, including transplant centers and surgeons, organ procurement organizations (OPO), commercial airlines, couriers, and other entities supporting end-to-end organ transplant logistics.

Currently, the organ transplant logistics approach provides little consistency, transparency, or traceability. Reports of organs being damaged, lost, delayed, or rendered unusable due to transportation issues have increasingly raised concerns about the nation's current organ transportation approach. 10 11

The 1984 National Organ Transplant Act (NOTA) requires the Health Resources and Services Administration (HRSA) to oversee the Organ Procurement and Transplantation Network (OPTN), which is responsible for allocating and distributing donor organs to individuals waiting for transplants. NOTA states the OPTN shall "coordinate, as possible, the transportation of organs and organ procurement organizations to transplant centers." Over the past few years, multiple Congressional and scientific reports highlighted the urgency to improve many aspects of the U.S. organ transplantation system, including increased transparency of and accountability for the chain of custody and transportation of organs procured for transplant. 12 13

In March 2023, HHS launched an initiative to modernize and improve OPTN to accelerate development and adoption of technology, data transparency and analytics, governance, operations, quality improvement, and innovation. ¹⁴ OPTN modernization focuses on better patient outcomes by improving the reliability, transparency, and performance of organ transplant logistics to minimize organ nonuse. To improve organ transplant logistics, HHS seeks to define requirements for a centralized organ transplant logistics system that allows for data capture, storage, analysis, and information sharing related to organ movement during the transportation process. A centralized organ transplant logistics system would allow for root cause analysis on adverse events and drive continual improvement and refinement of organ transplant logistics. To accomplish this, HHS must identify, evaluate, and develop existing or emerging technology solutions that accurately and reliably track an organ's location and condition, and provide that data into the centralized organ transplant logistics system. Trackability during organ transport, as well as data-sharing capabilities, will promote timely, safe transport of organs.

Improving the transport of donated organs requires understanding current organ transportation logistics and identifying challenges in transportation, tracking, and data-sharing technology and services that negatively impact the use of donated organs. To identify potential solutions, the Health FFRDC assessed technologies used by select companies in organ logistics, as well as sectors outside of healthcare. This analysis will help identify opportunities to use existing or emerging technologies to monitor organ location and other important variables, such as temperature, time to destination, chain of custody, or



clinical markers that assess the continued organ viability. In addition to identifying potential in-transit tracking solutions, an assessment of existing centralized logistics tracking systems, along with datasharing standards, can help inform requirements for a centralized organ transplant logistics tracking system.

Objectives

This report's objective is to identify current and emerging logistics tracking technologies, data standards, and systems used by private industry, the organ transplantation ecosystem, and the federal government. This report uses a scan of available literature and select interviews with logistics companies serving multiple industries, organ transplant logistics companies, and government logistics leaders.

Appendix A describes the methodology used along with the list of organizations interviewed. The report:

- 1. Describes the current state of organ transplant logistics, including challenges
- 2. Describes the tracking technologies available and most applicable to organ transplant and highlights technologies used by organ transplant logistics companies
- 3. Describes data standards and formats used across the logistics industry
- 4. Identifies commercial logistics systems used for logistics data exchange and information sharing

This report does not include information from interviews with OPOs, transplant centers, and other system users as those are forthcoming. Therefore, this report also does not recommend requirements or solutions.

Current Logistics and Challenges

When an organ becomes available for transplantation, OPOs and transplant centers must quickly and securely coordinate transport to the recipient center. The available preservation window, or cold ischemic time (CIT), varies by organ type, ranging from four to 36 hours. ¹⁵ Recent changes to OPTN organ allocation policies reduced the emphasis on geographic proximity, leading to increased travel distances for organs. In the first year of continuous lung distribution, the median travel distance nearly doubled. ¹⁶ These longer distances, combined with short preservation windows, leave little room for error or delays in transportation.

To transport organs, each OPO and transplant center coordinates with various commercial and private air and ground logistics providers, sometimes using different providers for different situations. These providers include couriers, ambulances, helicopters, commercial airlines, and private charter airlines, with varying levels of sophistication and tracking capabilities¹⁷ and no national standards for vendors and carriers. Each OPO and transplant center implements its own organ transportation process, ¹⁸ including selecting couriers, determining transportation modes, and routing methods. While OPTN policy specifies packaging, labeling, and documentation requirements using United Network for Organ Sharing (UNOS) TransNet system, it does not specify requirements for transportation other than policies for costs incurred.¹⁹

Transportation Challenges

Given the time-sensitive nature of organ transport and the need for coordination among multiple entities, logistical challenges are reported in both air and ground travel. According to an analysis using



UNOS data published by the Kaiser Family Foundation, seven percent of shipments handled by UNOS between July 2014 and November 2019 experienced transportation delays or failures. Half of these issues were linked to commercial airlines or airports. Two-thirds of the commercial airlines or airport issues were caused by weather delays, mechanical issues, and flight cancellations. Further complicating these commercial airline and airport challenges is that in some areas, commercial flights have limited evening and overnight departures, restricting the window for organ transport and offering limited flexibility for unexpected delays. Additionally, organs often travel unaccompanied in commercial aircraft cargo, occasionally being delayed or unaccounted for. The OPTN does not collect data about mode of organ transport, above or below wing transport on a commercial flight, cold ischemic time, or delayed organs; consequently, HHS currently does not know the number of organs transported by commercial airlines annually. While chartered flights provide more flexibility, they are significantly more expensive and less available. Notably, in May 2024, the Federal Aviation Administration (FAA) Reauthorization Act established a working group to develop best practices for transporting organs in commercial aircraft cabins within one year of convening.

In addition to air travel challenges, ground transportation challenges also exist; an estimated one-third of transportation problems are related to ground couriers, mainly involving delays in pickups and organs not being ready at the scheduled time. To Ground travel is often not an option for longer distances or rugged terrain, which can impact transport to and from rural communities. Compounding this challenge, procuring and transporting organs into and out of rural areas often involves more complicated logistics, increasing the likelihood of delays, missed connections, or other issues. It is reasonable to assert that improvements in the organ transportation and logistics data collection such as location tracking, especially for delays or transportation issues, routes and courier information, and modes of transportation may have a significant benefit for waitlist patients at small, rural, or otherwise remote hospitals.

In-Transit Tracking and Monitoring Challenges

In addition to transportation challenges, another set of challenges is related to lack of visibility in an organ's location and temperature during transport. Currently, OPTN policy does not require OPOs and transplant centers to track organ location nor condition while in transit. Reports of organs being left unattended or lost as well as concerns over organ transport in extreme temperature conditions underscore the need for visibility into an organ's location and temperature during transport. Without guidance from OPTN, some OPOs elect to incorporate tracking technologies into their transport process. The type of tracking technology and approach to use varies across OPOs.

Some OPOs use reusable tracking devices that need to be returned for reuse which is a barrier to uptake due to associated costs and complex processes. One former OPO CEO reported dedicating about one-third of a staff member's time to contacting transplant centers for the return of high-cost tracking equipment, despite including a pre-paid return envelope with the organ shipment. In response to these tracking challenges, UNOS launched the UNOS Organ Tracking Service in 2021, offering real-time location data, package updates, and automatic notifications. However, OPOs and transplant centers expressed concerns about this system, such as the lack of automated warnings for missed checkpoints



and reliability issues and called for improvements.¹¹The UNOS Organ Tracking Service has limited uptake by OPOs, reporting only 12 OPOs using the service as of January 2025.²³

Support Services: Data-Sharing and Reporting Challenges

A final category of challenges is the lack of requirements, processes, and information technology (IT) systems for standardized, national data reporting to HHS to determine when and why logistics challenges occur, despite the availability of several data tools and a centralized support service entity. The centralized support service, the UNOS Organ Center (formally known as the F.M. Kirby Foundation Organ Center), describes its work as collaborating "with OPOs, transplant hospitals and others to:

- Assist in placing donated organs (primarily kidneys) for transplantation
- Assist in gathering donor information and running the donor/recipient computer matching process
- Respond to requests for support in transporting organs and tissues for transplantation
- Act as a resource to the transplant community regarding organ-sharing policies" ²⁴

The vast majority of OPOs do not involve the Organ Center in recovered organ logistics, and when they do, the transportation couriers and methods are selected by the OPO and transplant hospitals involved in the transit.²⁵ ²⁶ For instance, in October 2024, the Organ Center facilitated only 24 total transportation arrangements on behalf of OPOs or transplant hospitals.²⁵ Colloquially known by some OPOs as the "OPO of last resort," the Organ Center is intended to help OPOs coordinate organ transportation when they have no other alternative. In addition, some smaller OPOs tend to use the Organ Center for logistics coordination more regularly.²⁷

While OPTN produces reports for HHS, there is limited transportation data. For the subset of organ transports facilitated, the Organ Center provides HHS with monthly summaries of the number and type of organs procured for transplantation, and the transportation method and responsible party (to include reallocated organs). OPTN also produces a Data Transmission and Summary Report for HHS.²⁵ Within this report, transportation data includes only the small subset of organ transports facilitated by the Organ Center because OPTN does not collect transportation data at the national level. The report includes the number and type of organs procured but not transplanted; however, the current "reasons not transplanted" list does not include "lost in transit" or other transportation failures. Moreover, in the month of October 2024, the OPOs did not report the non-utilization reason for 60% (n=629) of the organs procured but not transplanted (n=1037).²⁵ This is the only report HHS receives with logistics details.²⁶

Other existing systems with data include UNOS TransNet, which collects information such as organ check-in time and reshipment location, but as of October 2024 only 21% of transplant hospitals used it.²⁵ Since 2023, the OPTN Membership and Professional Standards Committee (MPSC) required transplant hospitals to report certain events to OPTN's Improving Patient Safety (IPS) web-portal within 24 hours. This reporting includes incorrect organ deliveries and transportation issues resulting in non-use of organs, but the level of detail and reporting in the IPS portal was not available for review.²⁸ Final organ disposition (transplanted or not transplanted) is not consistently or completely reported to HHS, limiting the ability to conduct root cause analysis on logistics challenges.



Logistics Technologies

Stakeholders in the organ transplant logistics ecosystem face an increasingly complicated challenge of trying to ensure organs are quickly and transparently moved from one location to another, while preserving the vitality of the organ. While modernizing this process will take investments and understanding of people and processes, technology also plays a critical role. There are three aspects of technology that are essential to modernize the organ logistics ecosystem:

- 1) In-transit tracking technologies
- 2) Data standards and Application Programming Interfaces (APIs) for data-sharing interoperability
- 3) Centralized system such as a real-time transportation visibility platform (RTTVP)

Tracking Technologies

In the logistics industry, companies use tracking technologies to monitor and collect information on the location and condition of shipments. These technologies are often not stand-alone technologies but are used in concert with each other. Therefore, the interoperability of devices – or the devices' ability to exchange information and work together – needs consideration. Location tracking and condition tracking promote the timely, safe transport of organs.

Location Tracking

Many stakeholders agree trackability during organ transport will help avoid adverse events, reduce organ nonuse, and maximize transplantation rates. Commercial logistics companies currently use four primary categories of tracking technologies to monitor a package's location – optical scanning (e.g., barcode), radio frequency identification (RFID), Bluetooth low-energy (BLE), and global positioning services (GPS) devices. Detailed information on these location tracking technologies is found in Appendix B, including a description, capabilities, examples of commercially available options, limitations, adoption across industry and use cases, and relevancy to organ transplantation. Each of these technologies have advantages and disadvantages when considering application to organ transplant logistics.

Optical scanning, such as barcodes or Quick Response (QR) codes, are the least expensive to use but their location can only be logged with a reading device such as an external scanner or a cell phone camera. The scanning device needs to be physically near the transported organ's container at the time of scanning to determine its location. UNOS attempted to standardize organ transplant barcode labeling in June 2017 with TransNet; however, data was not available to assess how frequently OPOs and transplant centers use these labels. RFID technology is slightly more expensive than optical scanning but still inexpensive (less than one dollar). RFID also uses a reading device to log location, but this device can be up to 10 meters away from the tagged organ container. RFID offers the beneficial ability of being automatically scanned (e.g., driving a car with a RFID tag such as E-ZPass through a toll booth with a RFID reader that automatic scans the RFID tag). However, RFID reading devices are not standardized nor widely available, a limiting factor to using RFID for organ transportation. Neither optical scanning nor RFID can generate real-time location data, an important feature for organ transportation modernization.



In contrast, BLE devices, while more expensive than optical scanning and RFID devices, can signal their location from almost anywhere. While the location signaling of BLE devices are appealing for organ transportation tracking, the device requires access to a network of finding devices, which are other BLE-enabled devices such as cell phones with appropriate software installed. BLE devices are ubiquitous in everyday life including fitness trackers and smart home and medical devices; however, commercial logistics companies are not frequently using these devices. Proprietary networks and narrow market applications limit the broad use of this technology for logistics. For example, Apple AirTags and Samsung SmartTags are similar functioning devices that require the presence of Apple and Samsung finding devices, respectively. Neither are interoperable. FedEx Custom Critical uses BLE technology to communicate and track sensitive shipments, such as vaccines during 2020.³¹

Finally, GPS devices are the most expensive of the four categories (\$50-\$200 per device)³⁰ and rely on a large network of geographically distributed satellites to generate location data typically transmitted using a cellular signal. Receiving the tracking data may require an additional subscription and can also be costly depending on the service required and number of devices. Devices that detect GPS location and then transmit that data require considerably more power, in comparison to BLE devices. These devices require larger internal batteries and require charging. Some device designs include solar panels to enhance longevity but require access to light; something that may not always be available throughout transport. To avoid battery life limitations, tracking technology can also be integrated into the transportation vehicle itself (e.g., truck, airplane) or a smartphone and its associated application tracks

the driver or pilot. A benefit of GPS devices is that performance is not degraded in remote areas. Rather than external GPS devices, several organizations across industries use cell phones and their applications to provide real-time location sharing with customers through applications, including Uber³² and DoorDash.³³ GPS from cell phones typically has less accurate location service than dedicated GPS devices, within about 65 feet, yet sufficient for most logistics applications.³⁴ The ubiquity of cell phones may be useful to track organs through

Interviewees highlighted the benefits of using courier smart phones to track shipments via the cell phone's embedded capabilities (e.g., GPS, BLE); however, noted that some couriers are resistant to installing tracking apps on their personal phones.

the courier's phone. In addition, several organizations interviewed participate in organ transportation and logistics – Paragonix Technologies, MNX UPS, TIVE, CareDX, and TransMedics – described using GPS tracking.

The biggest challenge interviewees experience with stand-alone GPS devices is when a receiving transplant center does not return the devices for reuse. Advancements in tracking technology and reduced development costs led to the emergence of single-use trackers as a potential solution to this challenge. One tracking technology organization described that approximately 80% of their customers use single-use trackers. The same organization also stated pricing of single-use devices is based on volume of purchases.



The maturity of organ logistics operations varies widely across geographic regions, which causes inefficiencies and interoperability issues between devices. Based on interviews with organ transplant logistics organizations, OPOs and logistics couriers use varied tracking technologies and require flexibility to select the tracking technology best suited for the environment and specific needs. For example, RFID tracking can only be effective if all partners can read the RFID tag information. The tracking technology should reflect the varied needs of organ transport logistics across OPOs. For example, complex shipments that involve multiple carriers may benefit from GPS tracking to ensure carriers complete handoffs. In a simpler logistics scenario, such as single courier transporting an organ a few miles, barcode tracking may suffice, though could easily be tracked via a GPS cell phone application. Therefore, in addition to the trackers themselves, the interoperability of devices – or the devices' ability to exchange information and work together – needs consideration.

Temperature and Condition Tracking

In addition to location tracking, entities involved in organ shipment and transplant are interested in monitoring the organ's temperature and condition during transport. Several organizations, including a former OPO CEO, discussed the need for temperature monitoring for informed decision-making and trust in the condition of the organ by the receiving transplant center. Pharmaceutical, food, and biotechnology industries also monitor temperature to protect against product degradation, spoilage, and regulatory compliance. These industries use temperature tracking devices to ensure that the "cold chain" remains unbroken, providing real-time data and historical records of temperature conditions throughout transit. These industries currently use three types of temperature trackers: 1) single use temperature indicators, 2) data loggers, and 3) real-time monitoring devices. Many commercially available temperature sensors are National Institute of Standards and Technology (NIST) certified to ensure precise temperature measurement. Detailed information on these condition tracking technologies is found in Appendix C, including a description, capabilities, commercially available options, limitations, adoption across industry and use cases, and relevancy to organ transplantation.

The most basic and cost-effective temperature sensor is single use temperature indicators. These indicators show a change in temperature through a visible chemical change, like a color change, when exposed to temperatures over time. Depending on the sophistication, these indicators can show single temperature exposure, multi-level temperature ranges, or indications of time (duration) and temperature exposure. These indicators are often used in the food and medical industries. For example, vaccine vial monitors using a heat sensitive indicator are found on all oral polio vaccines since 1997. In addition, the Centers for Disease Control and Prevention (CDC) used commercially available time and temperature indicators for shipping and storing biomedical test samples. 36

Data loggers record temperature at continuously or at predefined intervals. These devices can work independently, recording information on a built in USB-type device or can work in tandem with an RFID device for logging data and alerting when temperatures are out of range. Data loggers do not provide real-time temperature monitoring data transmission. Data loggers are inexpensive and often single use, an advantage for organ transplant logistics. Several defense logistics agencies discussed using temperature data loggers (e.g., Sensitech TempTale); one use case discussed was for blood product



shipments. Defense agencies indicated that one challenge with data loggers is not having the data until the shipment arrives and data is downloaded, which would also be a challenge in organ transport.

The most advanced and expensive temperature tracking is real-time monitoring devices. These trackers provide continuous temperature tracking and transmit data using the same technologies as location tracking, BLE, satellite, and cellular networks.

Some real-time temperature sensors are integrated with GPS location technology. These devices can provide real-time location tracking along with continuous temperature monitoring and transmit data at set intervals or trigger alerts if temperature thresholds are exceeded. However, the devices may have coverage gaps, such as in remote areas, or signal interference, such as in metal containers or airplanes.

One logistics company that monitors temperature cautioned that temperature accuracy can vary, and default monitoring ranges (e.g., +/-7C) can be narrowed with technology updates.

Organizations shared they also can have inconsistent device reliability in extreme temperatures or at altitude (e.g., when using air transport), especially when using the device for alarms or alerts. These could be limitations for use in organ transport monitoring. Additional factors to consider for organ intransit monitoring are that some devices may require programming or calibration, particularly if used multiple times. This reprogramming may require staff training, while some may require special software or company proprietary cloud subscriptions for data monitoring at an additional cost.

While temperature monitoring is a priority in organ transplant logistics, other condition monitoring variables are a consideration. One organization interviewed discussed sensors that capture temperature, humidity, light, and shock. Another organization shared that transplant centers did not know how to interpret the shock data or how to use it to inform decision-making. The Health FFRDC will seek more information through user interviews to assess the value of monitoring variables like shock, light, and humidity for informed decision making.

Data Standards and Exchange

HHS and organ transplant logistics stakeholders need access to data from when the organ is matched, throughout transportation, and until the organ's final disposition. Data exchange is driven by APIs, intermediaries that enable two software systems to communicate and share data. Data standards and APIs are foundational and necessary for retrieving, manipulating, and exchanging data in a centralized, accessible, data-rich system. While some logistics companies that transport organs are using data standards and APIs, there is not a widely used uniform data standard, and APIs are often company specific.

Data Standards and Formats

Data standards serve as a bridge between computer systems for data collection, exchange, and storage to enhance efficiency, reduce errors, and optimize data flow within business operations. However, benefits from data standards are dependent on the number of partners also using the same standard.



Developed over 35 years ago as a barcode standard and used in blood banks, ISBT 128 is a widely

endorsed "global standard to support the transfer, traceability, and transfusion/transplantation of blood, cells, tissues, and organs." ³⁷ Another data standard called Electronic Data Interchange (EDI) is a common data exchange standard historically used by bigger companies in the supply chain industry for communication between different

"One rule in supply chain data...everyone does whatever they want with respect to data" – Logistics Company operating a Real-time Transportation Visibility Platform

systems.³⁸ Several logistics and transportation organizations referenced EDI during interviews, however, many emphasized the industry lacks uniformity and consistently adopted standards. Variations of EDI are embedded in some legacy systems, especially the larger established players, but newer platforms are replacing these with web APIs whenever possible. Within healthcare, the Fast Healthcare Interoperability Resources (FHIR) standard defines the exchange of healthcare information, including clinical and administrative data.³⁹

The inconsistent standards used by organ transport logistics companies requires multiple, often non-automated, data integration methods to track organs from origin to destination. Interviews revealed a variety of methods to obtain data, including web scraping, and manual data entry. Web scraping is extracting data from websites that were not intended for automated usage. It typically consists of software entering a tracking number in a logistics courier's website in a manner similar to a person and then processing the results to extract the data. Other logistics companies are solely developing APIs for data exchange.

Data Exchange: Application Programming Interfaces

Companies use APIs to integrate real-time tracking information from various sources, such as GPS devices, warehouse management systems, and delivery platforms, into a central dashboard or platform. With an API, one application or system (i.e., client) sends a request to another application or system (i.e., server) which then fulfills the request and returns the requested data. For example, a mobile application sends a request for traffic data to a centralized source, such as a dispatch system or RTTVP, which then transmits the requested data back to the mobile application. The API is the set of rules and protocols that sits between these two applications and enables the application and system to share only the necessary and requested information without exposing either side to security risks. For organ transportation, APIs can facilitate sending item tracking to a centralized platform or potentially trigger alerts for when temperatures go out of range. 41 42

Any organization can define an API. However, when organizations forego creating new APIs and adopt existing one, the shared API becomes a standard. The more organizations that adopt them, the greater impact that API has. Such is the role of American National Standards Institute (ANSI) approved organizations, such as Health Level 7 International (HL7). Their focus, encouraged by the federal government, is to create open APIs which any organization can use without worry of intellectual property or licensing considerations, and which facilitate system interoperability and data exchange.



There are several ways that APIs work, the most common today being Representational State Transfer (REST) APIs. An organization that wishes to make its data available will develop, test, and document APIs thereby enabling other entities to systematically access its data system(s). For example, Pulse Charter Connect can develop an API to enable a RTTVP provider to request certain information from Pulse Charter Connect systems and incorporate it in the RTTVP. In this example, Pulse Charter Connect could make decisions like limiting the number of simultaneous requests or limiting the frequency of updates. Some companies provide tiered API access to these requests with associated costs. One organization that provides real-time transit visibility has an open API available to its organ transplant customers to push data out of its system but expressed it does not intend to open APIs to carriers or other partners to submit data to integrate into its platform.

APIs and associated data standards may also communicate over other protocols, such as Bluetooth, RFID, QR codes, and other mechanisms. Federal data exchange standards, such as FHIR, may exchange health data via RESTful APIs; or the data standard might be used via Bluetooth or RFID, called "FHIR-over-Bluetooth," or "FHIR-over-RFID" respectively. Similarly, data standards such as the ISBT-128 barcode used in blood banks might also be sent over RESTful APIs, Bluetooth, or RFID.

Real-Time Transportation Visibility Platforms

RTTVPs provide a single interface with a comprehensive, dynamic view of shipments as they move through the supply chain. RTTVP capabilities enable users to plan for cost and time for transport, track real-time location, communicate across stakeholders, and analyze trends and predict future outcomes. These platforms work with multiple logistics providers and tracking devices to assess different transportation options, provide visibility into tracking data, and offer analytics based on historical information.

RTTVP Systems Available

An RTTVP for organ transport logistics could provide foundational capabilities for modernization, thus select RTTVPs were examined to better understand the potential application. Dozens of logistics and supply chain RTTVP companies exist; to focus the research, the Health FFRDC examined Gartner's top three ranked companies, ^{a 44} project44, FourKites, and Shippeo. In addition, two RTTVP companies were interviewed about their platform capabilities, Shipium and Pulse Charter Connect, with Pulse Charter Connect solely focused on organ transplant logistics. Many companies have developed a unique proprietary RTTVP rather than using a commercial-off-the-shelf (COTS) product. This report does not provide a comprehensive view of the RTTVP market; rather, it explores common capabilities the RTTVPs provide today that are relevant to organ transplant logistics. A summary of these five companies and their platform description, key capabilities, limitations, adoption and use case, and relevancy to organ transplant logistics is found in Appendix D.

RTTVP companies offer varying capabilities and methods to plan for the time and cost of transport. Most platforms examined have capabilities to estimate delivery time, some provided this information directly

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^a Gartner reports are widely considered a useful first step to understanding industry major players and emerging trends. Companies are ranked in a Magic Quadrant provides "a graphical competitive positioning of four types of technology providers in fast growing markets: Leaders, Visionaries, Niche Players, and Challengers."



from the logistics organization. In addition, Shippeo and Shipium both refine delivery estimates using machine learning built into the system. The Pulse Charter Connect platform has a marketplace where logistic providers can bid on parts of the journey and OPOs can use the bid information to make decisions. Project44's platform states a similar capability.

All the RTTVPs reviewed track items in transit using various methods for sourcing location data. Methods for accessing location data include data feeds from logistics providers including a range of sources from manual bar code scanning to real-time location tracking, APIs, web scraping, and phone calls. ⁴⁵ The previously mentioned lack of consistency in data standards and tracking methods contributes to the wide variety of methods platforms need to use to keep users up to date.

In addition to visibility into the location of an item, the RTTVPs examined also provide communication updates to interested stakeholders. Most companies provide push communication via automatic notifications, email, and text messages. Some companies operate a centralized supply chain control tower, which includes trained experts, standardized processes, and monitors the RTTVP in real time, similar to air traffic control. ⁴⁶ Companies with this offer real-time status monitoring along with decision and execution support across an entire supply chain leveraging artificial intelligence (AI) and machine learning (ML). They also include messaging and electronic transaction capabilities that allow users to efficiently execute decisions with partners. Organ logistics organizations described adoption of aspects of the supply chain control towers, such as the ability to re-route a plane due to a snowstorm.

Innovations Ahead: Organ Transportation Support Service Control Tower for Real-time Monitoring
An organ transport logistics control tower would enable relevant parties such as the donor and
recipient transplant centers, OPO, and transportation courier to monitor the organ movement from
explant to transplant. Using the data inputs available these partners could make real time decisions to
ensure safe organ transport. For example, an organ procured in Chicago, Illinois starts its journey by
road to Cedar Rapids, Iowa around 6 p.m. Suddenly, a large traffic accident involving an 18-wheeler
occurs on a main highway along this route near Iowa City. The control tower experts use advanced
analytics to quickly identify alternative paths and help the transport team decide to use a helicopter to
move the organ over the blocked road, thus preventing the organ from sitting in traffic for hours.

The Health FFRDC's review demonstrates that the RTTVP COTS market provides capabilities that warrant further investigation for organ transport logistics. Unfortunately, no cost information for RTTVPs was publicly available. These platforms may offer accurate, up-to-date information on the location of an item but they are dependent on data from logistics providers. In cases where logistics organizations do not offer automated interfaces or those interfaces do not provide accurate information, that platform will reflect the lag and inaccuracy. However, given the available capabilities and multiple viable company products, available RTTVP's may be promising to adapt for an organ transport logistics centralized platform. The UNOS Tracking Service appears to offer an RTTVP capability. The full range of the capabilities offered to users was not available for review.



Artificial Intelligence and Machine Learning in RTTVP

Al and ML tools are often integrated into RTTVPs. Organizations use Al algorithms to analyze "messy" and unstructured data to optimize shipping routes and delivery times. They consider factors like traffic, weather, and historical performance to predict route times and provide route options. In addition, organizations use ML models to predict potential shipping disruptions and improve delivery time predictions. For example, Shipium uses Al and ML models to improve accuracy in shipping times using analysis of historical trends along with seasonality effects, weather, and other inputs allowing more efficient transportation planning. Likewise, TransMedics uses Al and ML models to provide scenario planning capabilities to support logistics planning decisions and to support agile decisions when an organ needs to be rerouted due to weather or other disruptions. In both cases, using Al and ML models allow for quickly integrating disparate data sets to find meaningful links that can inform decisions.

Application of RTTVPs in Organ Transplant Logistics

RTTVPs offer capabilities that could be foundational to operate and provide visibility into the organ transport logistics ecosystem. First, when transporting an organ, an RTTVP can share a cost and estimated arrival time. This typically involves obtaining cost and delivery time estimates from multiple logistics providers. An RTTVP could then show options to an OPO assisting them in selecting appropriate means of transportation. Second, when an OPO selects a logistics provider and transports an organ, RTTVP has the capability to provide real-time updates on its location and confirmation of delivery. Third, organ transport often requires communication between stakeholders which RTTVPs can enable. These communications can range from couriers alerting transplant centers of delays, to OPOs requesting rerouting based on changing situations. Finally, RTTVP captures data including historical information on previous trips. HHS can use this data to identify adverse events and near miss root cause analysis, performance improvement, and future decision-making.

Emerging Trends and Technologies in Logistics

Emerging trends and technology may enhance efficiency and predictiveness of transport. In addition to tracking and data visibility, the integration of emerging technologies has the potential to transform organ transport by shortening transport times or lengthening the time that an organ can remain viable. While these technologies hold promise, they need to mature for consistent use in organ transplant logistics. Near-time investments and requirements for tracking technologies, data standards, and a central data hub need to consider how to potentially accommodate these emerging technologies in the future.

Advanced Air Mobility

Several researchers are exploring the use of AAM, such as drone aircrafts or air taxis, to transport organs with the promise of faster transportation that can avoid urban congestion and offer faster straight-line routing in rural areas. ⁴⁷ Tests, using kidneys, have shown the potential to deliver organs successfully using AAM, but there are barriers to overcome, primarily the distance AAM aircrafts can operate, FAA regulatory considerations, and drone payload capacity. ⁴⁸ These studies tracked the condition of the kidney as well as environmental factors such as barometric pressure, vibration, and shock and found that AAM deliveries were comparable to, if not more stable than, commercial air transport. ⁴⁸ Models developed for rural AAM transportation show that using AAM can reduce rural transit times by almost



22 minutes compared to ground transportation.⁴⁶ While use of AAM shows promise to reduce organ transplant times without impacting organ viability, further exploration is needed to determine the best applications of AAM technologies to benefit the transplant community. In addition, collaboration with FAA is needed to ensure AAM organ transport complies with flight regulations.

Organ Perfusion Technologies

Organ perfusion technologies combine multiple monitoring technology features into one device and provide the capability to deliver warm perfusion to the organ for the entire time the organ moves from the donor to the recipient. The technology is tailored to each organ type; the market currently offers solutions for heart, lung, liver, pancreas, and kidney. The device is a layered organ transport container designed specifically for the needs of each organ that maintains temperature in a precise range and can also maintain and monitor pressure, PH levels, and oxygen levels. An example product includes the TransMedics Organ Care System (OCS) which can be used for heart, lung, and liver transplants. The advantage of this technology is the potential to transport longer distances and improve post-operative patient outcomes from a reduction in ischemic damage. While still evolving technology, organ transport logistics organizations expressed they commonly use organ perfusion systems.

Biosensors and "Organs-on-Chips"

Biosensors are analytical devices that combine a biological recognition element with a physical or chemical transducer. They detect and measure specific biological substances, such as proteins, DNA, or glucose. In the context of organ transport, biosensors can be used to: 1) monitor the levels of oxygen, glucose, and other vital metabolites in the preservation solution; 2) detect signs of organ damage or rejection; and 3) provide real-time feedback on the organ's viability.⁵⁰

Organs-on-Chips (OoCs) contain living cells and tissues, and they can replicate the complex physiological processes that occur in the body. OoCs offer a more accurate and realistic model of human organ function compared to traditional cell cultures or animal models. While OoCs are not yet widely used in clinical practice, the technology is rapidly advancing, with researchers developing chips that mimic various organs, including the heart, lungs, liver, and kidneys. In the context of organ transport, OoCs have the potential to: 1) assess the viability of organs before transplantation; 2) test the effects of preservation solutions and other treatments; and 3) provide a platform for developing new organ preservation techniques. ⁵¹ ⁵²

While these technologies have the potential for improving organ transport in the future, there are barriers to current use including the size of the devices, the need for additional sensitivity and specificity testing, and ensuring biocompatibility with living tissue.

Blockchain

Blockchain systems, initially designed in 2008, store and simultaneously share transactions and chronicle events with all entities involved in moving the item to provide visibility. This tracking and visibility serve as a barrier to tampering with the data, making any non-conforming transaction more easily identified. While this may seem beneficial for organ transplantation, establishing participants on a blockchain requires all the participants to invest in the integration infrastructure and set up the data mapping needed to send and receive information with the blockchain. Due to the complexity, cost, and



inflexibility, blockchain systems generally only make sense if stakeholders aren't willing to agree on a centralized, online, trusted third party to store and verify data. One blockchain company acknowledged most supply chains with a single source of truth, such as a central database, do not need blockchain because the central database provides visibility and accountability to satisfy most needs. In organ transplantation, the governance and use of a central visibility system will serve the trusted third party role as a centralized database. Also, using blockchain in organ transportation would likely limit the ability to add new transport partners. Therefore, the benefit of blockchain to organ transportation logistics is not evident at this time.

Limitations

This report has limitations in its findings given the methods used and additional information needed to fully describe the value of organ transport logistics. While the Health FFRDC conducted a broad scope of research to understand current and available technologies applicable to organ transplant logistics, interviews included only a small sample of organizations thereby representing limited perspectives. In addition, research for this report did not engage current and potential users of the technology discussed (planned for next phase of work), which are needed to develop recommended business requirements for organ transplant logistics. The support services provided by the Organ Center had limited publicly available information and the engagements conducted to date had little knowledge or experience with the Organ Center. As the work evolves, the Health FFRDC will engage with OPOs and transplant centers that use the Organ Center support services to understand the services provided. While developing the requirements, the Health FFRDC will also need to partner with HHS to better understand additional context of how a centralized organ transplant logistics visibility system may fit within the larger OPTN technology infrastructure to ensure the requirements are grounded in the larger OPTN modernization effort.

Discussion

HHS can address many of the organ transplant logistics challenges with existing technology; these solutions may be addressed through directions to the OPTN or providing additional operational support through contract services. However, the OPTN has not implemented logistics tracking technology or transportation data reporting requirements, leaving OPOs, transplant centers, and logistics partners making independent technology and reporting choices. HHS also needs a centralized organ transplant logistics system to enable the OPTN and its partners to make informed decisions to reduce damaged, lost, delayed organs for transplant. Finally, a centralized data collection for logistics and real-time logistics support system could enable stronger, data-driven HHS oversight of the OPTN and OPTN members to ensure that action is taken should patterns of loss, damage, or delay be identified.

The preliminary findings in this report reflect interviews with industry, government, and organ transplant logistics companies and information garnered from available literature. Next, the Health FFRDC will supplement the findings with system user needs by conducting interviews with OPOs, transplant centers, and logistics couriers. These interviews will bolster current findings on logistics



capabilities and identify additional challenges faced by OPOs, transplant centers, and their partners. Then, collectively, the Health FFRDC will use this information to build recommended business requirements HHS can use to improve the transparency and outcomes related to organ transportation.

The recommended business requirements will include:

- 1) Minimum OPTN requirements for OPOs, logistics providers, and transplant centers for using organ tracking technologies and data collection and reporting
- 2) HHS requirements for a centralized organ transplant logistics visibility system for data capture, storage, analysis, and information sharing

Given the high stakes' nature of transporting organs, HHS may need a phased or modular implementation of minimum requirements, enabling time for adaptation and incorporation of lessons learned.

Minimum OPTN Requirements for Organ Tracking Technology, Data Collection, and Reporting

As the organ transport logistics ecosystem looks to modernize, both location and temperature tracking

technologies are commercially available to provide data for informed decision-making. To determine the minimum tracking technology HHS should direct the OPTN to require along with the minimum data to collect and share, consideration must be given to the cost of real-time monitoring devices, OPTN transportation-related policies, and the system user needs for access to real-time data.

The government needs to set expectation for tracking, but not specify technologies, there needs to be room for "industry to innovate at the speed of industry" – Organ logistics organization

In the near term, HHS efforts should focus on identifying important data elements that OPTN data collection

should include, and determining how, when, and to whom to track and report data.

HHS requirements for a Centralized Organ Transplant Logistics Visibility System

As partners increasingly use tracking technology and HHS collects relevant data, HHS will need a system to collect, share, and analyze data for process and system improvement. This type of system will increase transparency, which stakeholders and the public have for a long time wanted, and in turn provides more accountability for each entities' performance. This centralized organ transplant logistics visibility system will also enable timely identification of challenges, root cause analysis for adverse events, and improved patient outcomes with maximum transplantation rates and minimum organ nonuse.

In the near term, efforts should focus on defining the primary users and use cases and identifying the minimum capabilities needed within this platform. In the longer-term, HHS can design and integrate more advanced capabilities as emerging technology develops and as the organ transplant logistics users



acquire new technology. These capabilities can use AI and ML tools, and other technologies to improve forecasting, performance monitoring, and other quality improvement needs.

Appendix A: Methodology

Two primary sources of information were used for this report: 1) scan of published and gray literature and 2) interviews with logistics companies and government organizations. Once data was collected and analyzed, the Health FFRDC synthesized information across the sources.

Literature Scan

The Health FFRDC searched key logistics and supply chain related journals, published and gray literature databases (e.g., <u>Gartner</u>, <u>Forrester Wave</u>, <u>Science Direct</u>) to identify key technologies the logistics industry uses. Search terms included combinations of the terms in Table 1:

QualifierProcessTechnologyDetail (optional)OrganLogisticsTrackingData standardsCold chainTransportationMonitoringCriticalArtificial intelligence/
machine learning

Table 1. Included search terms

The Health FFRDC assessed literature found for technologies related to logistics tracking and related technologies that could be applicable to the organ transplant ecosystem. Literature was reviewed for logistics tracking innovation (i.e., foundational, leading, innovative), breadth of use, financial cost (i.e., low, high), benefits, limitations, data standards and architecture described, and relevance to organ transplant transportation and logistics. Findings from the literature were systematically tracked in an excel spreadsheet for summary and synthesis.

Industry Interviews

The Health FFRDC also identified key government agencies and organ and industry logistics companies to inform the interviews. This initial exploration resulted in a list of 16 companies for outreach and interview. Twelve additional companies were also identified through discussions with HRSA and were added to the list later in the process. The Health FFRDC outreached to 30 organizations and conducted a total of 15 interviews with 14 organizations as of March 7, 2025. Of the organizations interviewed, seven



were organ transplant logistics or tracking organizations, three were industry logistics organizations, and four were government organizations. A full list of the organizations the Health FFRDC interviewed are found in Table 2.

Table 2. Logistics organizations interviewed

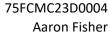
Organization Category Type	Organizations Interviewed
Organ transplant logistics or tracking experience	TransMedics
	Pargaonix Technologies
	BLADE Air Mobility
	Pulse Charter Connect
	MediGO/CareDX
	UPS MNX
	Tive
Industry logistics	Shipium
	ORBCOMM
	LandSeaAir
Government	Health Resources and Services Administration (HRSA)
	Centers for Medicare & Medicaid Services (CMS)
	Defense Logistics Agency (DLA)
	Medical Logistics Management Center (MLMC)

Before interviews were conducted, the Health FFRDC created an organization profile based on publicly available information. The Health FFRDC conducted 60 minute interviews via Microsoft Teams and included representatives from the organization of interest, a Health FFRDC facilitator, a note-taker, and HHS staff. Interviews were conducted between January 7, 2025, to March 7, 2025. The interviews were not recorded; however, the Health FFRDC staff developed detailed notes. Interview questions and facilitation guides were previously summarized in *Deliverable 1.1.1 Tracking Technology and Logistics Provider Interview Guides*. General topics discussed included current technologies or systems used to document, track, monitor and maintain shipments, data points collected, supply chain challenges, data sharing, and emerging technology.

The Health FFRDC identified key themes to analyze the interview notes including:

- Current and emerging technologies and related challenges
- Data collection, accessibility, use, sharing, and related challenges
- UNOS-related solutions
- Rural challenges and solutions

- Financial considerations
- Future capabilities and recommendations
- Future requirements for consideration
- Use cases and industry use
- Transportation modes





All interview notes were analyzed and findings were tracked in a spreadsheet for summary and synthesis.

Final Synthesis

The Health FFRDC synthesized information from the literature and interviews to summarize technologies across industry, organ logistics, and government and the potential applicability to the organ transplant logistics challenges. In addition to technologies, the Health FFRDC considered data standards, interoperability, and systems used by these organizations to manage the transportation logistics.



Appendix B: Description of Tracking Technologies for Location Monitoring

Technology	Description	Key Capabilities	Examples – commercially available	Limitations	Adoption and Use Cases	OT Relevancy
Optical Scanning (e.g., Bar Code, QR code)	Inexpensive tracker needs adjacent external reader, typically a laser scanner External readers are widely available (e.g., cell phone camera)	Captures product information, time stamps, location can be manually or electronically recorded (not automatic)	Zebra DS3608-SR Honeywell Xenon XP 1950g	Need scanner near package to read No real-time location information	Widespread Use in a variety of package sizes from small retail to large shipping	 Inexpensive Widely available and many options for bar code readers No real-time location information available
RFID	Inexpensive "tags" that need external reader within 10m; Read using radio wave interrogators External readers are not widely available Can be automatically scanned	Captures product information, time stamps, location can be manually or electronically recorded (not automatic)	Zebra MC3330RHoneywell EDA51	Need scanner to read up to 10 meters from package No real-time location information	Widespread use Used in retail, toll collection, animal control and other asset tracking.	Inexpensive RFID readers not widely available or standardized, all partners would need Can be automatically read at short distance No real-time location information available
Bluetooth-low energy (BLE)	Relatively inexpensive Use low energy connection to connect with nearby Bluetooth- enabled devices which report the device location and signal strength to a central system that triangulates the location data to provide an accurate location	Captures product information, time stamps, and real-time location tracking	Apple AirTag Tile Mate Samsung SmartTag	Limited commercial use to date would necessitate piloting to ensure tags produce the needed data and the data are accessible	Used primarily for personal belonging tracking Relatively inexpensive Some logistics companies are exploring use Not interoperable between proprietary networks; (e.g., Apple AirTags require Apple BLE-enabled finding device)	Low cost Real-time location tracking Requires access to other BLE-enabled finding devices (e.g., cell phones) with requisite software Not interoperable between proprietary networks



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Technology	Description	Key Capabilities	Examples – commercially available	Limitations	Adoption and Use Cases	OT Relevancy
Global Positioning System (GPS)	Device collects information from multiple satellites and triangulates to determine location Cellular network to transmit the location information; antenna receives signal from the GPS satellites Some devices include integrated memory and can log position and time readings which can be accessible later in the absence of transmission networks Can be a separate GPS device or integrated cell phone and application	Captures product information, time stamps, and real-time location tracking	LandAirSea 54 Orbcomm GT1000 Tracki GPS SamsaraAG26 (offers temperature and humidity monitoring)	Expensive, especially if tracking individual items as opposed to a shipment of many goods	Widespread Used across a range of logistics applications including package tracking and routing Performance not degraded in remote areas Update frequency can be configurable, with more frequent updates coming at the expense of battery life	 Expensive Complex reverse logistics if returning and reusing GPS device; single-use trackers are available Real-time location tracking Need to consider battery life Uses a data generation and transmission approach that is ubiquitously available Can track package itself, the driver/pilot, or transportation vehicle Several organ transplant logistics companies are using - Paragonix Technologies, MNX UPS, TIVE, CareDX, and TransMedics

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Appendix C: Types of Temperature Trackers

Technology	Description	Key Capabilities	Examples -commercially available	Limitations	Adoption and Use Cases	OT Relevancy
Single Use Temperature Indicators	Provides a visual indication of temperature excursions Some indicate duration of temperature excursion	Temperature excursions identified; no "technology" needed Cost effective Single use	 3M MonitorMark Temperature Indicators ColdMark Temperature Indicators WarmMark Temperature Indicators 	Does not provide detailed data logging.	Used in food industry	 Inexpensive and single use (no reverse logistics to return) Needs visual inspection No data record
Temperature Data Loggers	Record temperature data continuously or at pre-defined intervals Uses either a built in USB-type device, or can work in tandem with RFID or BLE technologies Identifies potential temperature excursions	Creates a historical record of data Can send alerts for temperatures out of range Cost effective Often single use	 Elitech RC-51H Temperature Data Logger Sensitech TempTale Ultra Fit Onset HOBO MX2301A 	 Most require manual retrieval of data after the shipment has arrived with limited opportunities for real time intervention. Because temperature is recorded at pre-set intervals, sudden spikes may be missed depending on the interval calibration. 	Used in food storage and transportation; pharmaceutical and life science applications	Inexpensive and often single use (no reverse logistics to return)



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Technology	Description	Key Capabilities	Examples -commercially available	Limitations	Adoption and Use Cases	OT Relevancy
Real-time Monitoring Devices	Provide continuous temperature tracking and transmit data using the same technologies as location tracking: BLE, satellite, and cellular networks.	 Can send real- time alerts for temperatures out of range GPS tracking 	Samsara AG26 Tive TT-700	Most expensive; may have additional costs for cloud-based data services to capture real time information May have gaps in remote areas or signal interference in metal containers or airplanes. Inconsistent reliability in extreme temperatures or at altitude (when using air transport), the device alerts May require programming or calibration. Power consumption and battery life concerns	Used in food industry; pharmaceutical industry	Expense may be a limiting factor Battery life is a general concern but less relevant given organ transports required short transit time Need to better understand reliability with signal interference, or extreme temperatures/altitude

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Appendix D: Select Real-Time Transportation Visibility Platform Systems Capabilities Overview

RTTVP	Description	Key Capabilities	Limitations	Adoption and Use Cases	OT Relevancy
project44	Enrolls carriers and shippers into its network Uses APIs to exchange data into its visibility platform Primarily caters to large retail manufacturers supplying bigbox and grocery store retail Offers extensive tools to improve logistics system inefficiencies	Provides cost quotes and book directly with carriers Includes Tracking information from network of 240k+ organizations Connects with carriers via mobile app, telematics tracking, and APIs Communicates shipment alerts Predict and prevent disruptions Combines AI-powered digital workers with traditional control tower capabilities to automate responses to issues Offers AI enhancements, such as "Movement AI" to improve transportation planning and monitoring	Not yet profitable, despite strong revenue and customer growth, as they prioritized innovation over profitability	Automotive, chemical, food & beverage, manufacturing, life sciences, and retail industries Customers include AstraZeneca, FedEx, Goodyear, LG, Lenovo, Ford, Whirlpool, Grainger, Sephora, General Mills, ABInBev, and McKesson	Key capabilities useful for organ transplant logistics including cost and time estimates, real-time tracking, API integration, disruption prediction, and control tower real- time issue response
FourKites	Sells to shippers and enrolls logistics services providers, collecting and sharing data from both Primarily caters to large retail manufacturers supplying bigbox and grocery store retail. Offers extensive tools to improve logistics system inefficiencies	Unclear if it provides cost and time estimates Tracks item movement in a unified view Includes Tracking information from network of 1.1M organizations Predicts and prevents disruptions Provides alerts when shipments are at risk Enables shippers to integrate the visibility into their own platforms Uses APIs to exchange data into its visibility platform Control tower capabilities to automate responses to issues	Unclear if it provides cost and time estimates Lower number of implementation partners and office locations than its competitors.	Retail, consumer packaged goods, food & beverage, manufacturing, health & life sciences, and oil & gas sectors Customers include Dow, Eastman, Nestle, Yamaha, Tetra Pak, Walmart Canada, Kraft Heinz, Best Buy, Coca Cola, and T-Mobile	Key capabilities useful for organ transplant logistics including real-time tracking, API integration, disruption prediction, and control tower real-time issue response Experience monitoring critical shipments, including temperature-sensitive items, with risk alerts Strong financial position



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RTTVP	Description	Key Capabilities	Limitations	Adoption and Use Cases	OT Relevancy
Shippeo	Links shippers, third-party logistics (3PL) providers, and carriers in a visibility platform Incorporates "Transportation Process Automation' using AI/ML to deliver advanced capabilities	Uses ML to provide time estimates with arrival accuracy guarantees; unclear if cost estimated Predicts and avoids disruptions, reducing transportation costs (no comparative transportation quotes) Provides real-time tracking information and delivery estimates to their customers Includes tracking information from network of 258K organizations Carriers and logistics providers can integrate both their transportation management system and telematics data Control tower capabilities to automate responses to issues Uses a digital twin and control tower to model processes and perform scenario analysis	Does not appear to have strong experience in healthcare or in sensitive/critical item shipments Primary market is Europe with some recent expansion in North America	Automotive, retail, industrial manufacturing, chemicals, and consumer packaged goods Customers include Imperial Brands, Tereos, Schneider Electric, Fujifilm, Leroy, TEDi, TotalEnergies, Krone, Rubix, and Fressnapf	Does not have strong presence in North America, healthcare, or sensitive and critical item shipments Key capabilities useful for organ transplant logistics including guaranteed time estimates, realtime tracking, API integration, disruption prediction, and control tower real-time issue response Uses AI/ML to deliver advanced capabilities
Shipium	Software company that utilizes software supply chain optimization technology to inform shipment decision making Manages primarily small package shipments, including selecting the package carrier and tracking the delivery from order through receipt Collects tracking data from carriers and provides it in a consistent, consolidated format to shippers and receivers	Uses ML with carrier estimates to provide time estimates Estimates price based on customer contracts set on the platform Provides item location primarily on event tracking data from bar code scans Collects data from suppliers using a combination of APIs, web scraping, and EDI Information available to users via the portal In some cases, APIs are used to create a tracking ID, build and print the shipper's label Offers shippers and receivers visibility into performance trends and analysis based on shipment tracking and past customer behavior Simulates the impact of future shipping changes to enhance decision making	Relatively new company (five years old) Focused on consumer goods Shipium does not directly manage the execution of courier logistics Unclear if has a control tower real-time issue response	Retail, logistics service providers and third-party logistics, business-to-business, and ecommerce Customers include Saks Off Fifth, Duluth Trading Co, AEO, GameStop, Standvast, Quiet Platforms, DCL, True Classic, Grove Collaborative, Redbubble	 Business model is not designed for managing the higher urgency logistics for transplant organs, focused on consumer goods Key capabilities useful for organ transplant logistics including cost and time estimates, real-time tracking, API integration.



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RTTVP	Description	Key Capabilities	Limitations	Adoption and Use Cases	OT Relevancy
Pulse Charter Connect	Mission is to improve and streamline organ and surgical team logistics to increase number of successful transplants across the country Provides real time visibility in tracking status on platform with automated notifications	 Provides cost marketplace where logistics providers price their "bid" on an organ movement and the OPO and transplant center can decide between multiple bids on the platform Provides real time tracking data with some data collected through voice and text communications with couriers based on logistics events and stage gates View historic shipments on platform 	Can reroute organ (to same destination) No mention of ability to predict future outcomes	 Focus on organ transplant logistics Customers include Keystone Perfusion Services, P.C. 	 Designed specifically for organ transport logistics Real-time visibility platform Data analysis tools and techniques unclear



Appendix E: Acronym List

Acronym	Definition
AAM	Advanced Air Mobility
ANSI	American National Standards Institute
API	Application Programming Interface
ASC	Accredited Standards Committee
BLE	Bluetooth Low Energy
CDC	Centers for Disease Control and Prevention (
CIT	Cold Ischemic Time
COTS	Commercial Off the Shelf
DOT	Department of Transportation
EDI	Electronic Data Interchange
FAA	Federal Aviation Administration
GPS	Global Positioning Service
HHS	Department of Health and Human Services
HL7	Health Level 7 International
HRSA	Health Resources and Services Administration
IPS	Improving Patient Safety
MPSC	Membership and Professional Standards Committee
NIST	National Institute of Standards and Technology
NOTA	National Organ Transplant Act
ocs	Organ Care System
OoCs	Organs-on-Chips





Acronym	Definition
ОРО	Organ Procurement Organization
OPTN	Organ Procurement and Transplantation Network
QR	Quick Response
REST	Representational State Transfer
RFID	Radio Frequency Identification
RTTVPS	Real-Time Transportation Visibility Platforms
UNOS	United Network for Organ Sharing



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