### **Cure**<sup>®</sup> White Paper

#### September 2024



# Improving Organ Transplantation with New Technology

Organ transplantation is a huge and rapidly growing segment of the health care industry. The aging of the population coupled with the rise of diseases such as diabetes and high blood pressure increase the risk of organ failure in more and more people.

In the United States, a record <u>46,000-plus</u> organ transplants were performed in 2023, according to the U.S. Department of Health & Human Services Organ Procurement & Transplantation Network. The total U.S. transplantation market is estimated to be worth more than \$15 billion today, and it's <u>growing</u> at a compound annual rate of 9.3 percent.



The total U.S. transplantation market value



It's compound annual rate is growing

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But the demand for organs continues to outpace the supply. The U.S. <u>waiting list</u> for organs exceeded 114,000 as of September 2024, with most patients waiting for kidneys. More than 38 percent of all potential transplant patients will be on the waitlist for more than two years.

New technologies for preserving organs for transplant could reduce wait times and make transplantation a realistic option for more patients.

Technology innovators are also developing genetic tools for surveilling patients post-transplant, which could improve outcomes. But pickup of these new technologies has been slow, as transplant providers grapple with hurdles such as payer pushback.

In April 2024, the <u>Deerfield Institute</u>, a division of Deerfield Management Company, an affiliate of Cure, surveyed 26 U.S. transplant surgeons about lung, liver, heart and kidney transplants performed at their facilities. They asked the surgeons about current transplant trends and their predictions for the future, including their impressions of technologies designed to improve organ viability and outcomes. Their insights are described here for the first time.

# Improving Organ Viability and Longevity

Each type of organ type has a tailored distribution framework, according to the <u>United Network</u> for Organ Sharing (UNOS). Among the factors considered for making a best-match of an organ with a recipient are the blood type and size of the organ needed, the recipient's wait list time, and the distance between the donor and recipient. Other factors include medical urgency, immune system matching, and recipient age, such as being a child or adult.

UNOS reports that the organ donation and transplant community are working to bring more equity to the system when allocating deceased donor organs. Such efforts aim to address well-documented inequities in organ transplantation. For example, studies show that black patients with kidney disease <u>wait for a kidney transplant</u> for one year longer on average than white patients do.

# Percentage of NOP users likely to increase utilization during the next five years (n = 19).



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In recent years, transplant centers have started experimenting with perfusion technology, which preserves donated organs by continuously pumping blood into them and keeping them warm. This marks a major change over the traditional method of keeping organs on ice until they're needed. Perfusion can lower the risk of organ damage — a problem that renders an estimated 70 to 80 percent of donated thoracic organs kept in cold storage unusable for transplant. Perfusion also allows donated organs to stay viable while transported over longer distances than what's possible with cold storage.

A leading profusion provider, TransMedics National OCS (Organ Care System) Program (NOP), is used by 73 percent of the facilities of respondents to Deerfield's survey. Facilities that procure NOP organs reported good outcomes: 90 percent of NOPprovided hearts were used, as were 92.5 percent of livers and 79.2 percent of lungs. Among NOP users, 53 percent reported being satisfied overall.

Still, several respondents cited cost as an impediment to adoption of NOP. "Highly effective in reducing ischemia reperfusion injury but cost is an issue," said one surgeon who reported being very satisfied with the OCS program. Another respondent, who reported being dissatisfied, commented that the perfusion service is "too expensive, and an impediment to organ transplant equity."

Most of the 19 surgeons whose facilities currently use NOP predicted future use will grow: 36 percent said their facility was likely to increase their use of the service for donated livers within five years, 50 percent predicted increased usage for hearts, and 57 percent expected a growth in usage for lungs. However, they do not predict that the number of liver or hearts procured through NOP will overtake those using a standard cooler method in the next five years.

Deerfield's survey indicated rising interest in alternatives to the NOP service that have been introduced in recent years — and that may help mitigate cost concerns. They include the XVIVO Kidney Assist, Liver Assist and XPS system for preserving lungs, Paragonix LUNGguard, LIVERguard and SherpaPak for hearts, and OrganOx metra system for livers.

One respondent from a liver-transplant facility said its team was considering switching to the OrganOx perfusion service "so we can pump more livers at less cost." The competing service might also make it possible "to place the liver on pump after cold storage," the surgeon added.



#### **Rates of rejection are HIGH**







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#### Use of dd-cfDNA testing

<50%	All Transplantations
45.1%	Kidney Transplantations
45.7%	Heart Transplantations

#### DNA Testing for Post-Transplant Surveillance

Another emerging technology in organ transplants is a diagnostic tool called donor-derived cell-free DNA (dd-cfDNA), a blood test that can be used to monitor the health of organs after transplantation. Monitoring patients is vital for detecting signs of acute organ rejection. Rates of rejection are <u>high</u>:

30 to 40 percent for transplanted hearts, 35 to 45 percent for lungs, 13 to 30 percent for livers and 12 to 14 percent for kidneys. When rejections are detected early, physicians can adjust dosages of anti-rejection therapies to improve patient outcomes.

The Deerfield survey revealed that dd-cfDNA testing is currently used in less than 50 percent of heart, lung, liver and kidney transplants. The tool is most popular among surgeons performing heart and kidney transplants (45.7 percent and 45.1 percent usage respectively).

But securing insurance reimbursement is a hurdle that's impeding the widespread adoption of ddcfDNA testing. One respondent reported that payers are restricting the use of dd-cfDNA testing to "for cause" patients, meaning those who are already exhibiting symptoms of organ rejection. That means testing for surveillance would not be reimbursed. Another noted that burdensome documentation requirements from Medicare is an impediment to adoption.

#### The Future of Organ Transplants

Deerfield's organ transplant survey demonstrates that surgeons are not only open to trying new technologies for preserving organs and improving patient outcomes, they're eager to bring these new tools into mainstream practice.

But in this field, where every second can mean the difference between life and death, payer resistance is a major hurdle. Removing this and other barriers to adoption will be essential for transplant providers to be able to keep up with the growing demand for donated organs.

#### One organ donor can save eight lives

Visit UNOS' Organ Procurement and Transplantation Network (OPTN)

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#### **About Cure**

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