ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

BOARD OF DIRECTORS

FORMAL POLICY SUBMISSION

A Lean Six Sigma Methodology for Transformation of the

United States Solid Organ Transplant System

End-to-End Process Analysis, Root Cause Investigation, Evidence-Based Reform, and a Comprehensive Policy Enforcement and Accountability Framework

Author	Jeff A. Parke
Version	Version 1.0
Date	June 2026
Submitted To	OPTN Board of Directors
Website	coldischemia.foundation

OPTN Board of Directors: Complete Roster (Terms Beginning July 1, 2025)

Source: HRSA (2025b). Board members vetted for independence and adherence to conflict-of-interest policies.

Board Officers

Role	Name	Institution / Affiliation
President	John C. Magee, MD	University of Michigan
Vice President	Shelley Hall, MD	Baylor University Medical Center
VP, Patient/Donor Affairs	William (Bill) Ryan, MBA	Transplant Life Foundation
Treasurer	Alan Reed, MD, MBA, FACS	University of Iowa / Iowa Health Care Organ Transplant Center
Secretary	Justin Wilkerson, MBA	Illinois Army National Guard; Liver Transplant Recipient

Transplant Physician and Surgeon Representatives

Name	Role / Institution
John C. Magee, MD	Attending Surgeon, Division of Transplantation; Prof. of Transplant Surgery, Internal Medicine and Pediatrics, University of Michigan
Alan Reed, MD, MBA, FACS	Prof. and Chief of Transplant and HPB Surgery, Iowa Carver College; Director, Iowa Health Care Organ Transplant Center
Dan Meyer, MD	Chief of Heart Transplantation and MCS; Chair of Cardiovascular Surgery, Baylor Scott and White Health, Dallas
Shelley Hall, MD	Chief of Transplant Cardiology, CHF and MCS, Baylor University Medical Center
Kymberly D. Watt, MD	Medical Director, Liver Transplantation Program; Professor of Medicine, Mayo Clinic
George Bayliss, MD	Medical Director, Division of Transplantation, Rhode Island Hospital; Professor of Medicine, Brown University

Joseph Magliocca, MD	Prof. of Surgery and Pediatrics; Executive Director, Vanderbilt Transplant Center; Surgical Director, Pediatric Liver Transplantation, Vanderbilt University Medical Center

Patient, Donor, and Family Member Representatives (9 of 35 seats = 26%)

Name	Background / Affiliation
John J. Sperzel III, BS	Previously Chairman and CEO, T2 Biosystems, Inc.
Gitthaline (Candie) Gagne, USN, HM1 (Ret.)	Previously Level 3 Surgical Technologist, UPMC McKeesport; Retired U.S. Navy Hospital Corpsman
Justin Wilkerson, MBA	Deputy Director of Human Services, Illinois Army National Guard; Liver Transplant Recipient
Peter Nicastro, MS, MBA	Previously Finance Director, Cigna
Jen Benson, BA	CEO and Founder, The Transplant Journey Inc. and The Transplant Collective; Pancreas and Kidney Transplant Recipient
James Cason, MA	Previously Mayor of Coral Gables, FL; Former U.S. Foreign Service Officer
Cody Reynolds	Father of a Pediatric Transplant Recipient
John Hodges, MA	Previously Faculty Research Assistant, Center for Remote Sensing, Boston University
William (Bill) Ryan, MBA	Founder, President, and CEO, Transplant Life Foundation; Family Member of a Deceased Donor

OPO, Transplant Hospital, and Non-Physician Representatives

Name	Role / Institution
Samantha Endicott, MPH, CPTC	Senior Director, Organ Optimization, New England Donor Services
Darren Lahrman, MBA, CPTC, BSRC	Executive Director, LifeLink of Florida
Kevin Lee, MPA	President and CEO, Mid-America Transplant
Joshua Gossett, DNP, MBA, RN, FACHE	Director, Pediatric Transplant Center, Lucile Packard Childrens Hospital Stanford
Annette Needham, DNP, NP-C, NEA-BC, CCTC	Transplant Quality Manager, UC Davis Transplant Center; Secretary, NATCO Board of Directors
Cathi Murphey, PhD, MS	Histocompatibility and Immunogenetics Laboratory Director, Southwest Immunodiagnostics, Inc.
Jerold Mande, MPH	CEO, Nourish Science; Adjunct Professor, Harvard T.H. Chan School of Public Health; guided development of original NOTA
Mary E. Homan, DrPH, MA, MSHCE	Mountain Region VP of Theology and Ethics, CommonSpirit Health

Regional Councillors

Region	Name	Institution
Region 1	Nahel Elias, MD	Medical Director for Quality, Division of Transplantation, Massachusetts General Hospital
Region 2	Kenneth Chavin, MD, MBA, PhD	Director of Abdominal Organ Transplant, Temple University Health System
Region 3	Ari Cohen, MD, MBA	Director, Ochsner Transplant Institute; Director of Transplant Research, Ochsner Health System
Region 4	Ryan Davies, MD	Clinical Director, Pediatric Heart Transplantation and MCS, UT Southwestern / Childrens Medical Center
Region 5	Andrew M. Courtwright, MD, PhD	Associate Professor of Clinical Medicine, Department of Pulmonary and Critical Care Medicine, University of Utah

Region 6	Gina-Marie Barletta, MD	Medical Director, Pediatric Kidney Transplantation, Oregon Health & Science University
Region 7	Reynold Lopez-Soler, MD, PhD	Professor of Surgery, Division of Transplant, Loyola University Medical Center; Section Chief of Renal Transplant, Edward Hines Jr. VA Medical Center
Region 8	Mark Wakefield, MD	Director and Primary Surgeon, Renal Transplant Program, University of Missouri Health Care
Region 9	Meelie DebRoy, MD	Section Chief, Kidney Transplant, Department of Surgery, Westchester Medical Center
Region 10*	Austin Schenk, MD, PhD, FACS	Quality and Patient Safety Officer, Comprehensive Transplant Center; Associate Professor of Surgery, Ohio State University
Region 11	Vincent Casingal, MD	Chief, Division of Abdominal Transplant; Surgical Director, Adult and Pediatric Kidney Transplant, Atrium Health-Carolinas Medical Center

** Austin Schenk, MD, PhD, FACS, assumed Region 10 Councillor role when John C. Magee, MD, was elected Board President.*

COLD ISCHEMIA FOUNDATION

Structural Healthcare Advocacy | Ellenton, Florida (FL-16)

A Lean Six Sigma Methodology for Transformation of the

United States Solid Organ Transplant System

End-to-End Process Analysis, Root Cause Investigation, Evidence-Based Reform, and a Comprehensive Policy Enforcement and Accountability Framework

Jeff A. Parke

Founder, Cold Ischemia Foundation

Lean Six Sigma Practitioner | Pharmaceutical Clinical Development Operations

Prepared for review and consideration by

Organ Procurement and Transplantation Network (OPTN) Board of Directors

Health Resources and Services Administration (HRSA) Organ Transplant Branch

Centers for Medicare & Medicaid Services (CMS) Quality Division

Peer-reviewed transplantation and health policy journals

Version 2.0 • June 2026

coldischemia.foundation

Executive Summary

Thirteen people died waiting for a kidney transplant today. Not because medicine has reached its scientific limit. Not because the organs do not exist. They died because a governance architecture built over forty years has been constructed, whether intentionally or through sustained institutional inertia, to protect the financial interests of organizations that benefit most from keeping patients on dialysis rather than moving them to transplant. That is a provable statement. This document proves it.

The Cold Ischemia Foundation applies Lean Six Sigma's DMAIC framework, Define, Measure, Analyze, Improve, Control, to the full kidney transplant value stream at the national policy level. What emerges is not a system at the edge of its scientific capabilities. It is a system with a process cycle efficiency of 0.5 percent (CIF analysis, 2026), a key quality metric that has been out of statistical control since 2021 (Montgomery, 2020), and a living donor pipeline losing 92.8 percent of potential donors to addressable barriers before a single donation is completed (Hays et al., 2019; UNOS, 2026).

In 2025, the United States performed 49,064 organ transplants, a record (UNOS, 2026). In that same year, kidney transplants declined for the first time in any non-pandemic year of the 21st century, producing 27,573 procedures, a net decrease of 102 from 2024 (UNOS, 2026). The deceased-donor kidney non-use rate peaked at 27.9 percent in 2023 and remained above 25 percent through 2025 (Lentine et al., 2025). More than one in four kidneys recovered from donors willing to give their organs after death was discarded.

"The transplant system does not have a knowledge problem. It has an accountability problem. Every reform proposed in this document has a named owner with specific legal authority. Every named owner has, year after year, chosen not to act."

The CMS Increasing Organ Transplant Access Model, launched July 1, 2025, is the most significant payment reform in the history of U.S. transplant policy (CMS, 2025). For the first time, a federal payment model explicitly rewards transplant volume and organ utilization alongside survival outcomes. But IOTA covers only 41 percent of kidney transplant hospitals, expires June 30, 2031, contains no living donor provisions, and faces an unresolved tension between its achievement and quality domains (CMS, 2025). IOTA is proof of concept. It is not, by itself, reform.

The Cold Ischemia Foundation accepts zero pharmaceutical, dialysis, or insurance industry funding. That independence is the structural prerequisite for this analysis. Fresenius Medical Care and DaVita together control approximately 70 percent of the U.S. dialysis market (USRDS, 2023). Each successful kidney transplant eliminates approximately $145,000 in annual dialysis revenue (USRDS, 2023). Organizations that accept dialysis industry funding while advocating for transplant access are operating under a conflict of interest whose consequences are visible in thirty years of comprehensive reform proposals and incomplete implementation.

Acknowledgments

The Cold Ischemia Foundation is a grassroots structural healthcare advocacy organization founded on a single constitutional constraint: zero pharmaceutical, dialysis, or insurance industry funding, ever. This constraint is the organizational condition that makes the analysis in this document possible. The author discloses no financial conflicts of interest. No pharmaceutical, dialysis, device, or insurance industry funding was received in connection with this work. All data sources are publicly available and fully cited. Analytical frameworks are drawn from published Lean Six Sigma methodology literature (George, 2003; Pyzdek & Keller, 2018; Montgomery, 2020). Policy positions represent the official position of the Cold Ischemia Foundation and not of any federal agency, professional society, or academic institution.

Jeff A. Parke, Founder, Cold Ischemia Foundation, Ellenton, Florida 34222. Website: coldischemia.foundation.

1. The Burning Platform: What Is Actually Happening Right Now

1.1 A Record Is Not a Success Story

When UNOS announced in January 2026 that the United States performed 49,064 organ transplants in 2025, the fifth consecutive annual record (UNOS, 2026), the headline traveled well. What it obscured is that kidney transplants, the single largest category serving the single largest waitlist, declined for the first time in any non-pandemic year of the 21st century. 27,573 kidney transplants were performed in 2025, a net decrease of 102 from 2024 (UNOS, 2026). Deceased donations fell 2.5 percent. The overdose-death donor pool shrank from 16.7 percent of deceased donors in 2022 to 10.5 percent by early 2025 (Kidney Transplant Collaborative, 2025). Donation after circulatory determination of death now accounts for nearly 50 percent of all deceased donors, and DCD kidneys carry meaningfully higher delayed graft function rates than donation after brain death kidneys (UNOS, 2026). The system is processing a harder raw material at the same time it is losing procurement capacity.

More than 90,000 people are waiting for a kidney right now, with 11.4 percent of them having waited five years or more (Lentine et al., 2025). Approximately 13 patients die every day on the kidney waitlist, a figure that has not materially declined in more than a decade (Lentine et al., 2025). The transplant system set an all-time record and simultaneously produced fewer kidney transplants than the year before. That is the precise definition of a system whose aggregate metrics are concealing a structural failure.

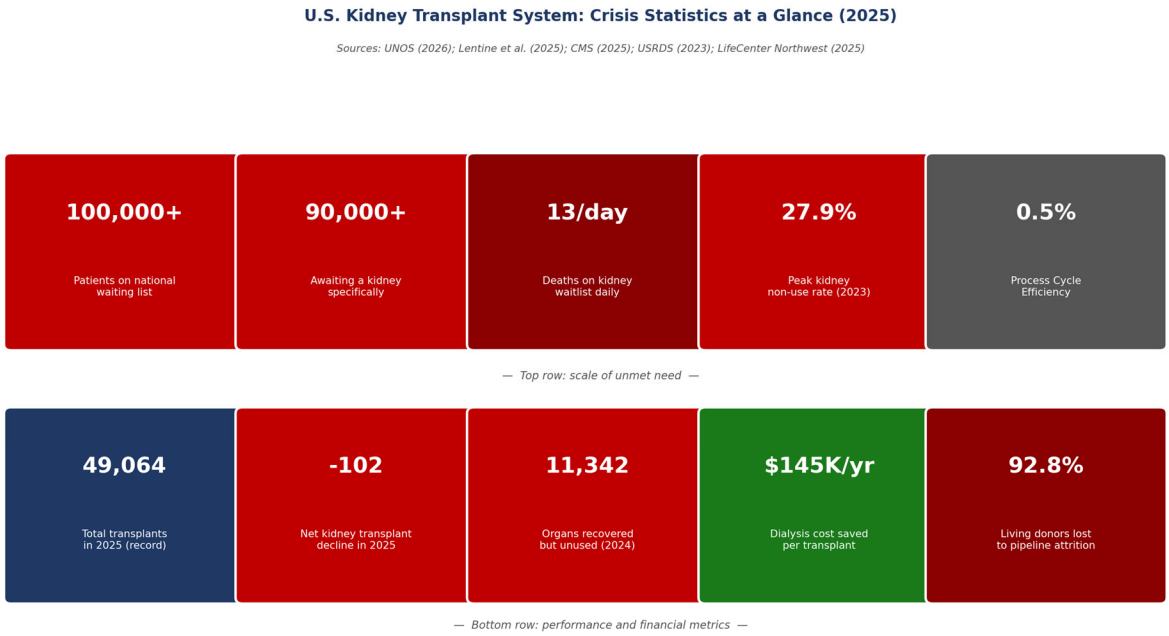

Figure 1. The U.S. Kidney Transplant System: Crisis Statistics at a Glance (2025). Each statistic represents a documented performance failure, not a natural limit of what transplant medicine can achieve. Sources: UNOS (2026); Lentine et al. (2025); CMS (2025); USRDS (2023); LifeCenter Northwest (2025).

"100,000 people waiting. 13 dying every day. A record transplant year. Both of those things are simultaneously true, and their coexistence is the scandal."

Non-use rates in specific donor strata reveal how far the system is from its clinical ceiling. The non-use rate for biopsied kidneys is 41.4 percent, for donors aged 65 or older it is 72.2 percent, and for kidneys with a Kidney Donor Profile Index at or above 85 percent it reaches 72.5 percent (Lentine et al., 2025). These figures do not represent the limits of what medicine can accomplish with these organs. They represent the limits of what the current incentive architecture will permit transplant centers to attempt.

1.2 The IOTA Model: The Right Direction, Insufficient Scope

On July 1, 2025, the Centers for Medicare and Medicaid Services launched the Increasing Organ Transplant Access Model, a six-year mandatory alternative payment model covering 103 kidney transplant hospitals across approximately 41 percent of the nation's Donation Service Areas (CMS, 2025). For the first time in U.S. transplant payment history, a federal model explicitly rewards transplant volume and organ utilization at the center level alongside survival outcomes. That structural shift directly addresses the Nash equilibrium documented in the Five-Whys analysis in Section 4.

IOTA's limitations must be stated plainly. It covers 41 percent of hospitals, expires June 30, 2031, contains no living donor provisions, and leaves the quality metric tension between accepting difficult organs and maintaining one-year graft survival rates unresolved (CMS, 2025). The December 2025 proposed rule acknowledged this tension without resolving it. Without codification into permanent Conditions of Participation before 2031, every hour of institutional adaptation disappears at expiration. The Cold Ischemia Foundation's position is that IOTA's direction is correct and its limitations are reform targets requiring urgent action before the countdown clock runs out.

1.3 Why Lean Six Sigma Belongs in This Conversation

The transplant system has measurable defects, identifiable customers, quantifiable process variation between centers, regions, and demographic groups, and documented root causes amenable to specific countermeasures. These are the precise characteristics for which Lean Six Sigma was developed (George, 2003; Pyzdek & Keller, 2018). The Lean component, derived from the Toyota Production System (Ohno, 1988) and formalized by Womack and Jones (1996), identifies and eliminates waste across the value stream. The Six Sigma component measures process performance identifies root causes through structured analytical tools, and establishes statistical control mechanisms that detect drift before it becomes catastrophe (Montgomery, 2020).

What distinguishes this application from prior quality improvement work in transplant settings, which has been primarily center-level and clinical in scope (Antony et al., 2018; Mader, 2007), is the addition of a policy enforcement lens applied at national scale. The transplant system does not lack well-documented reform proposals. It lacks the process discipline to implement them and the accountability architecture to sustain them. That is a process control problem with a process engineering solution.

2. Mapping the System: Where Value Is Created and Where It Is Destroyed

2.1 What the Patient Actually Experiences

A patient with end-stage renal disease who enters the transplant pathway in the United States in 2026 faces a value stream with a total lead time of 3.8 to 7.2 years depending on blood type, geographic location, panel reactive antibody sensitization level, and transplant center practice variation (OPTN/SRTR, 2023). The value-added time during that period, meaning active evaluation, surgery, and immediate post-operative care, is approximately 14 days (CIF analysis, 2026; Womack & Jones, 1996). Process Cycle Efficiency equals value-added time divided by total lead time, producing approximately 0.5 percent. In plain engineering terms, 99.5 percent of the time this system consumes from the patient's perspective generates no clinical value. That time is not neutral. Every month on dialysis carries measurable cardiovascular damage, cognitive decline, infection risk, and quality of life destruction (USRDS, 2023).

If a candidate changes transplant centers for any reason, including insurance change, geographic relocation, or excessive wait times at their original program, the evaluation process restarts entirely. Workup results are center-specific and non-portable, meaning the time, cost, and cleared barriers at the first center vanish. This duplication serves no patient or donor; it serves only institutional convenience.

2.2 Seven Categories of Lean Waste, All Present, All Preventable

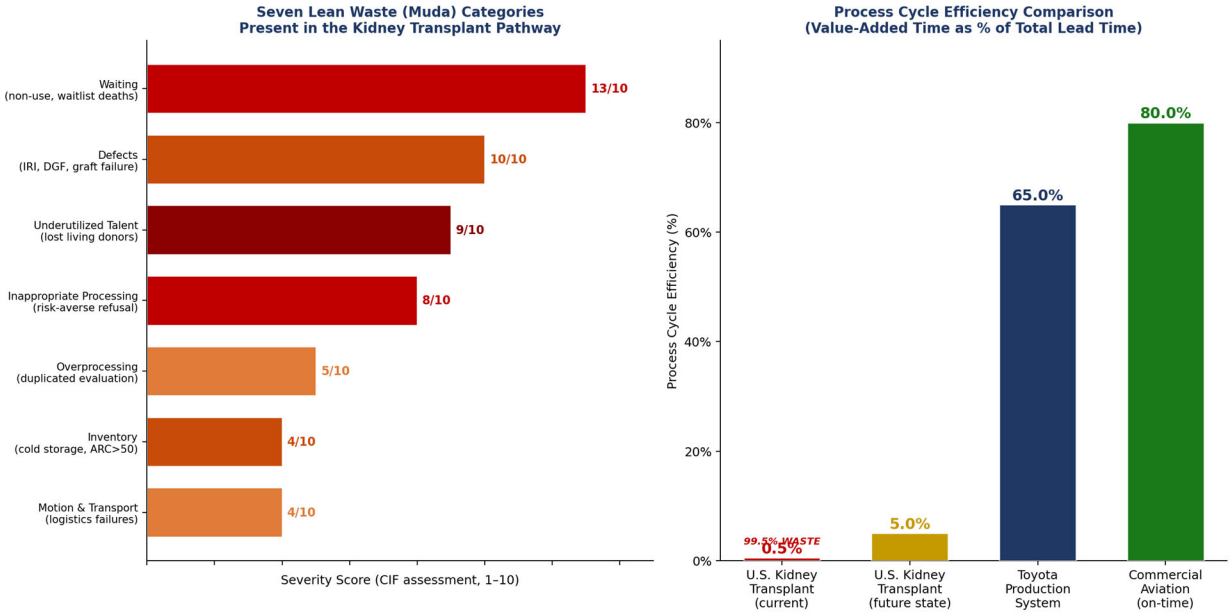

Figure 2. LSS Waste Analysis: The Kidney Transplant System as a Lean Engineering Problem. Left panel: seven Lean waste (Muda) categories present in the kidney transplant pathway, scored by severity. Right panel: Process Cycle Efficiency comparison showing the U.S. transplant system at 0.5% against other high-stakes process environments. Sources: Lum et al. (2023); UNOS (2026); Womack & Jones (1996); CIF process analysis (2026).

Lean methodology identifies seven categories of process waste, known as Muda, and every one appears in the kidney transplant pathway. Waiting is the dominant waste category: the 27.9 percent non-use rate, median waitlist time of 3 to 5 years, and 13 deaths per day on the waitlist (Lentine et al., 2025). Overprocessing appears as duplicated evaluation testing across centers without portable workup standards (OPTN/SRTR, 2023). Defects include delayed graft function, which rises from 20.9 percent at optimal cold ischemia time to 37.5 percent in the 32 to 40-hour stratum (Lum et al., 2023). Underutilized Talent is the lost living donor pool, representing 92.8 percent cumulative attrition from initial consideration to completed donation (UNOS, 2026; Hays et al., 2019). Motion and Transport waste consists of commercial flight courier delays that add avoidable cold ischemia hours, with McKenney et al. (2024) finding transportation difficulties are now the primary discard reason for machine-perfused kidneys. Inventory waste appears as organs in extended cold storage during sequential refusal cycles, with Accumulated Refusal Counts routinely exceeding 50 for kidneys ultimately discarded (Stewart et al., 2026). Inappropriate Processing is risk-averse organ refusal driven by CMS quality metrics that penalize poor one-year outcomes more heavily than they reward utilization (CMS, 2025).

None of these waste categories requires new science to address. Each requires policy will, enforced standards, and aligned incentives. The Process Cycle Efficiency comparison in Figure 2 makes the scale of the failure visible: at 0.5 percent, the U.S. transplant system operates at a fraction of the efficiency expected from any other high-stakes process environment, and the consequence of that inefficiency is measured in lives.

2.3 The DMAIC Framework at National Scale

Define: The project charter targets a 25 percent reduction in waitlist mortality by Q4 2028, 10,000 living donor kidney transplants per year by 2030, and a kidney non-use rate below 15 percent by 2028. These targets are derived from what international benchmarking demonstrates is achievable within the current scientific environment, not from aspirational optimism (ONT, 2025; ANZDATA, 2025). Measure: Current-state performance is characterized using statistical process control analysis, six-year trend data, and cross-national benchmarking against Spain, France, and Australia. Analyze: Root causes are identified using Ishikawa, Pareto, and Five-Whys tools across both the living donor pipeline and the deceased-donor non-use problem. Improve: Eleven specific countermeasures are proposed with named owners, enforceable timelines, and linkage to specific root causes. Control: Gains are sustained through SPC governance with mandatory response triggers, regulatory codification in CMS Conditions of Participation, public performance dashboards, independent annual audit, mandatory Congressional reporting, and structural patient representation on the OPTN Board.

3. Measuring the Crisis: Six Years of Data That Cannot Be Rationalized Away

3.1 The Six-Year Trend

Between 2020 and 2023, deceased-donor kidney transplants grew from 17,600 to 22,800 annually while the non-use rate simultaneously climbed from 22.0 to 27.9 percent (UNOS, 2026; Lentine et al., 2025). More recovered organs, more discarded organs, the same number of people dying on the waitlist. In 2025, the first meaningful improvement in the discard rate in 25 years was not enough to prevent the first kidney transplant decline in any non-pandemic year of the 21st century (Kidney Transplant Collaborative, 2025). The living donor share of kidney transplants has sat at 22 to 24 percent for six consecutive years, unmoved, while the clinical evidence for living donor superiority in graft longevity and recipient outcomes has strengthened each year (Lentine et al., 2025).

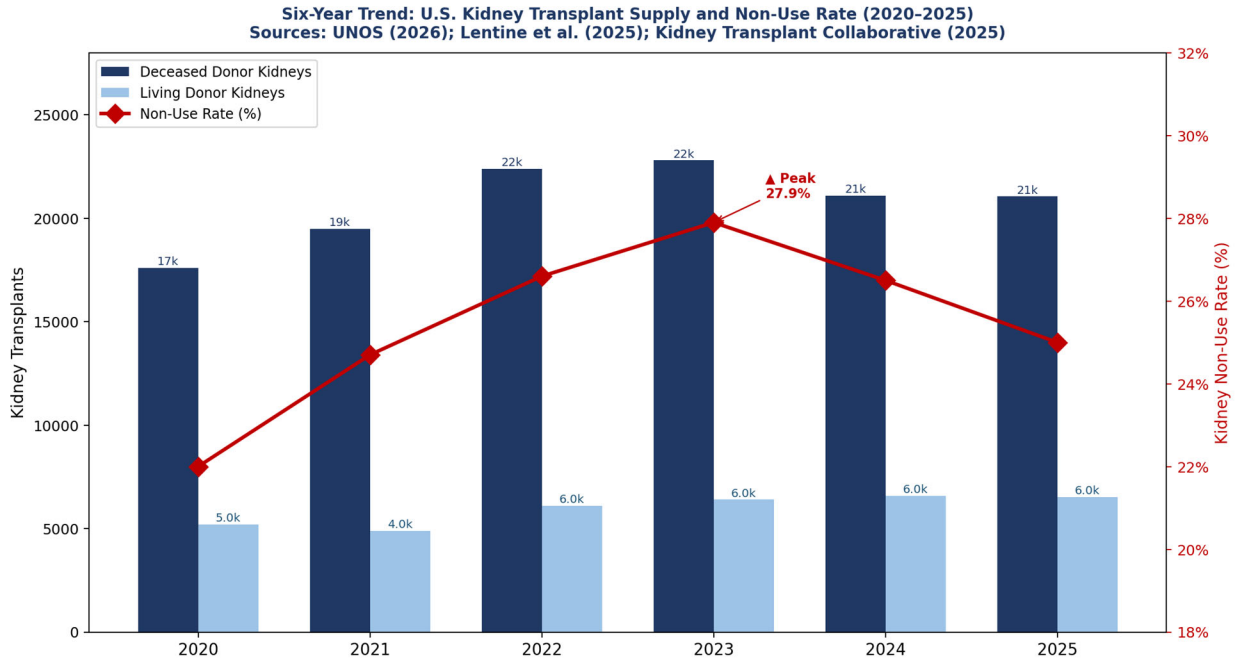

Figure 3. Six-Year Trend: U.S. Kidney Transplant Supply and Non-Use Rate (2020–2025). The living donor share has not moved in six years despite overwhelming clinical evidence for living donor superiority. The 2025 non-use rate is estimated. Sources: UNOS (2026); Lentine et al. (2025); Kidney Transplant Collaborative (2025).

Barrier-stack modeling documents that 92.8 percent of potential living donors are lost to addressable barriers before completing donation (UNOS, 2026; Hays et al., 2019). A 5 percent improvement in pass-through rates at each of six major filter stages would increase completed donations by approximately 35 percent, from roughly 7,200 to nearly 9,700 annually, representing more than 2,500 additional kidney transplants per year at no increase in deceased donor organ supply (CIF analysis, 2026). The federal policy apparatus is not structured to capture this gain because it is invested in the wrong interventions.

3.2 The SPC Chart: Out of Statistical Control Since 2021

Plotted as a statistical process control chart with control limits established at plus or minus three standard deviations from a pre-KAS250 baseline mean of approximately 22.1 percent, the kidney non-use rate exhibits the classic signature of a process that has undergone a mean shift (Montgomery, 2020). Before KAS250 implementation in March 2021, which removed Donor Service Area geographic boundaries and expanded organ sharing to a 250-nautical-mile radius, the non-use rate exhibited common-cause variation consistent with a stable process. After KAS250, the rate climbed through 24.7 percent in 2021, 26.6 percent in 2022, and 27.9 percent in 2023, breaching the upper control limit (UNOS, 2026; Lentine et al., 2025). That breach satisfies Nelson Rule 1: a process is no longer in statistical control (Montgomery, 2020).

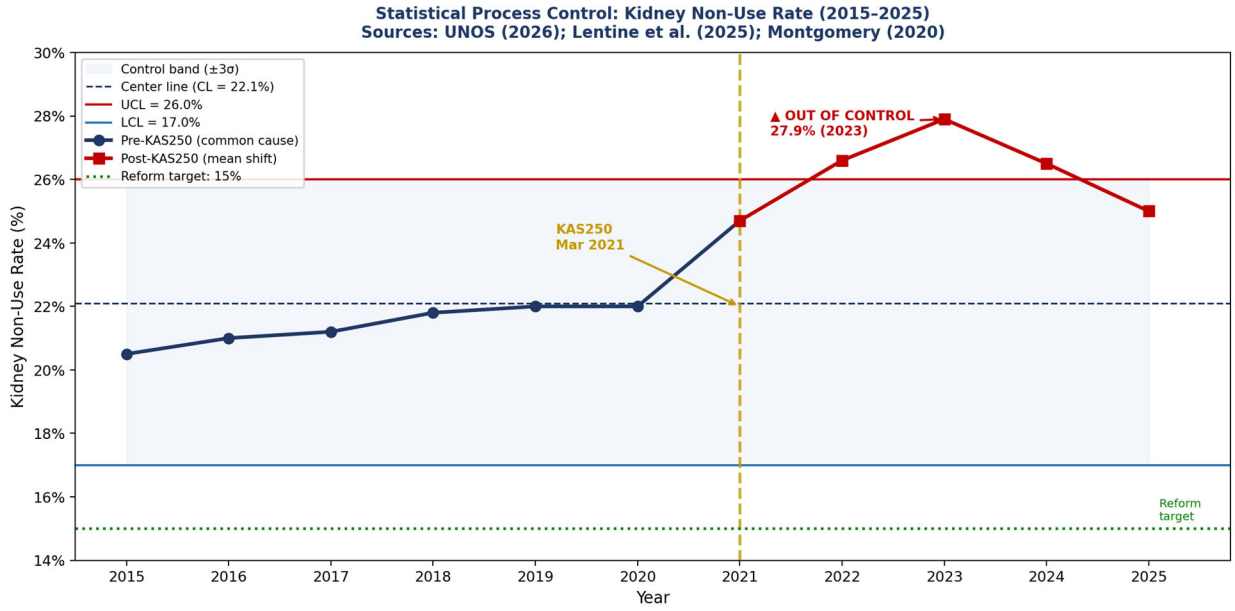

Figure 4. Statistical Process Control Chart: Kidney Non-Use Rate (2015–2025). Control limits established at ±3σ from pre-KAS250 baseline (≈22.1%). The 2023 data point satisfies Nelson Rule 1 (one point beyond 3σ). The reform target of 15% is consistent with Spain's documented performance and would represent approximately 3,500 additional transplants annually. Sources: UNOS (2026); Lentine et al. (2025); Montgomery (2020).

The practical significance of the out-of-control finding is that the system cannot be corrected through incremental adjustment until the mean-shift mechanism is identified and addressed. The Five-Whys analysis in Section 4 identifies that mechanism: KAS250 expanded geographic distribution without any corresponding update to organ acceptance logistics infrastructure, OPO coordination protocols, or CMS quality metrics. The policy intended to improve equity in allocation inadvertently increased cold ischemia time and gave transplant centers more financially rational reasons to decline offers. The policy was implemented without the process control infrastructure to detect and respond to its unintended consequences. HRSA's February 2025 formal directive identifying out-of-sequence allocation noncompliance adds a further dimension: the distribution expansion also created conditions in which OPOs began making offers outside the match run sequence, a practice HRSA has now characterized as violating federal regulations (HRSA, 2025a).

The reform target of 15 percent non-use, consistent with well-performing European systems (ONT, 2025), would represent approximately 3,500 additional kidney transplants annually and a corresponding reduction in waitlist deaths. Every year the system remains above that target, the

gap represents preventable deaths attributable to identifiable policy decisions by identifiable actors.

3.3 OPO Performance Variation: Measuring the Wrong Things

The 55 Organ Procurement Organizations operating across the United States exhibit performance variation so substantial it constitutes a structural measurement failure. LifeCenter Northwest, in a 2025 analysis of its CMS Tier 2 classification, documented that it had increased organ donors by 34 percent and transplant-eligible organs by 32 percent between 2020 and 2024, yet its CMS tier fell below the top 25 percent (LifeCenter Northwest, 2025). The mechanism is a methodological error: CMS OPO metrics attribute discard decisions made by transplant centers to the OPO responsible for the donor's service area, structurally penalizing OPOs for transplant center behavior they do not control (LifeCenter Northwest, 2025).

The NBER analysis of the 2019 OPO accountability reform found that replacing self-reported metrics with standardized, independently verified measures increased kidney procurement by 29 percent among high-performing OPOs and generated approximately $359 million in net fiscal savings through 2023 (Ozbay et al., 2025). However, Bradbrook et al. (2025) found that 75 percent of the increase in kidney discard is attributable to donor pool composition changes, specifically the shift toward older and higher-comorbidity donors, rather than OPO performance failures. The policy design challenge is creating metrics that distinguish true OPO performance from case mix effects. The current CMS tier system has not solved this, and the IOTA Model does not directly address it.

4. Finding the Root Causes: Why the System Fails the Same Way Every Time

4.1 The Living Donor Problem: A Decade of Flatline

Living donor kidney transplantation produces better outcomes than deceased-donor transplantation by every major clinical measure, including longer graft survival, lower delayed graft function rates, and better long-term recipient health. The evidence has been overwhelming and consistent for decades (Lentine et al., 2025). Yet the U.S. living donor share of kidney transplants has not moved, sitting at 22 to 24 percent year after year while the waitlist grows. The Ishikawa analysis identifies a root cause environment that is distributed across six categories, and every root cause is policy-addressable within current federal regulatory authority.

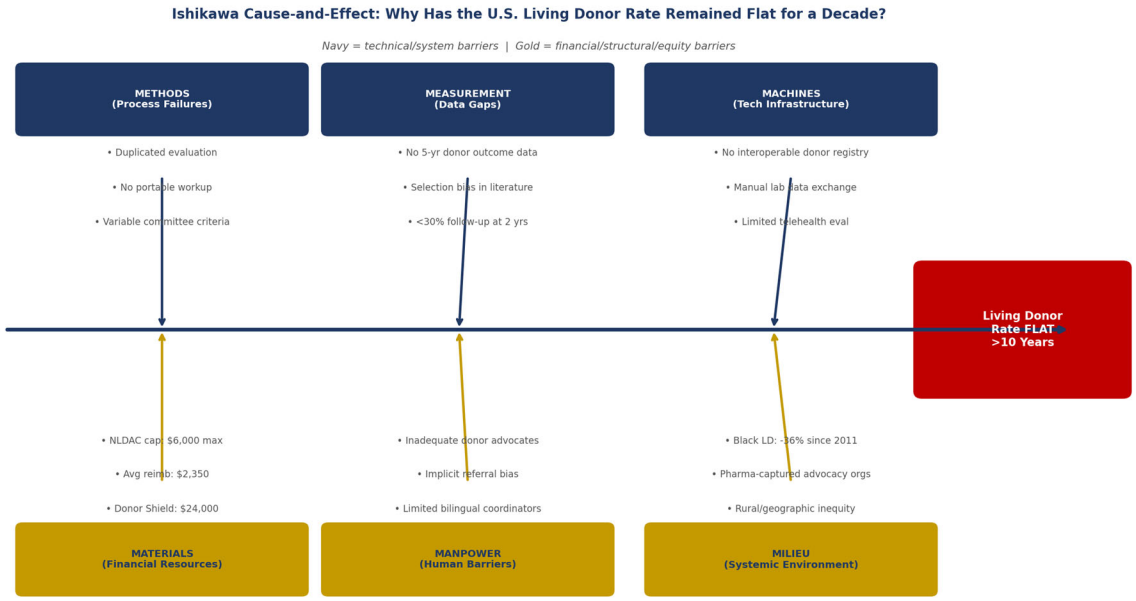

Figure 5. Ishikawa Cause-and-Effect Diagram: Why Has the U.S. Living Donor Rate Remained Flat for More Than a Decade? Navy bones indicate technical and system barriers. Gold bones indicate financial, structural, and equity barriers. All root causes are addressable within current federal regulatory authority without changes to organ donation law. Sources: CIF analysis; Hays et al. (2019); Dew & Jacobs (2012); Klarenbach et al. (2014).

Methods barriers: Evaluation is duplicated across transplant centers with no portable workup standards (OPTN/SRTR, 2023). A candidate who changes programs must restart entirely, losing every cleared hurdle. This duplication serves no clinical purpose and imposes time and financial burdens on potential donors without improving their safety or the system's performance.

Measurement barriers: Follow-up beyond two years is rare in the U.S. system, and at five or ten years it is effectively absent (ANZDATA, 2025). This is not an academic gap. It is a donor safety failure being manufactured in real time. Adverse outcomes that emerge years after donation, including accelerated chronic kidney disease progression, cardiovascular events, and psychosocial sequelae, are being systematically undercounted because the system chooses not to track them.

Materials barriers: The National Living Donor Assistance Center provides a maximum combined reimbursement of $6,000 for travel, lodging, lost wages, and dependent care, with average actual reimbursement of approximately $2,350 per donor (Hays et al., 2019). Total donor out-of-pocket costs range from $3,200 to $5,500 at minimum (Klarenbach et al., 2014). The program conditions eligibility on the recipient's income rather than the donor's financial need, meaning donors whose recipients have any meaningful income may be ineligible even when donation would impose genuine financial hardship on the donor. The National Kidney Registry's Donor Shield program covers up to $24,000 in private coverage (National Kidney Registry, 2023). The gap between $2,350 and $24,000 is a policy choice.

Equity barriers: The Black living donor share fell from 11.9 percent in 2011 to 7.6 percent in 2022, a 36 percent relative decline during a decade in which overall living donation was growing (Lentine et al., 2024; Patzer, 2024). Native American kidney transplant rates declined 14 percent from 2011 to 2021 (Patzer, 2024). These trends do not emerge from neutral demographic processes. They emerge when financial barriers go unaddressed in communities that cannot absorb them, insurance discrimination goes unfederated, and outreach programs are designed for high-health-literacy populations while deployed in communities where kidney disease burden is highest.

4.2 Pareto Analysis: The Federal Government Is Funding the Wrong Interventions

When living donor attrition is ranked by root cause and analyzed through a Pareto lens, four causes account for 68 percent of all candidate loss: financial and lost-wage barriers at approximately 26 percent of total attrition, insurance discrimination at approximately 17 percent, lengthy evaluation processes at approximately 14 percent, and family and caregiver logistics at approximately 11 percent (Hays et al., 2019; Dew & Jacobs, 2012; Klarenbach et al., 2014). All four have available federal legislative or regulatory solutions requiring no changes to organ donation law or clinical transplant standards.

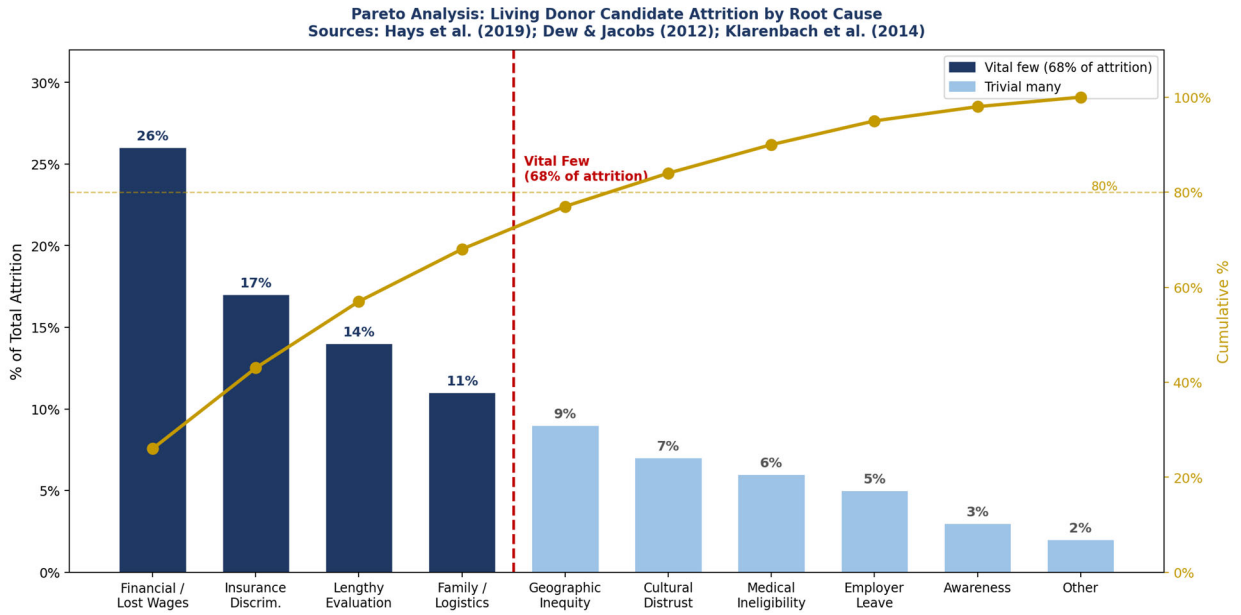

Figure 6. Pareto Analysis: Living Donor Candidate Attrition by Root Cause (per 1,000 initiated evaluations). The vital few, four causes accounting for 68% of all attrition, are shown in navy. Public awareness campaigns, the most common federal investment

in living donor promotion, address the 9th-ranked cause at approximately 3% of attrition. Sources: Hays et al. (2019); Dew & Jacobs (2012); Klarenbach et al. (2014); CIF analysis (2026).

Public awareness campaigns, the most common federal investment in living donation promotion, address the ninth-ranked cause of attrition, accounting for approximately 3 percent of all candidate loss. The federal government is systematically investing in the tail of the Pareto distribution while the vital few causes, collectively explaining two thirds of all donor loss, remain substantially unaddressed. This is not a resource problem. It is a priority problem driven by the path of least political resistance.

4.3 Five-Whys: The Nash Equilibrium That Kills People

Applied to the 27.9 percent non-use rate, the Five-Whys methodology terminates at a structural misalignment between federal allocation policy and CMS quality metrics that has persisted for more than a decade despite broad professional recognition (Stewart et al., 2026; CMS, 2025; HRSA, 2025a). Individual transplant centers decline marginal kidneys because their quality metrics penalize poor one-year graft survival more heavily than they reward utilization. Each refusal adds cold time, making the organ appear worse to the next center in the sequence, making the next refusal more likely. The logistics chain depends on commercial flights without real-time tracking. At the root, federal allocation policy seeks population-level utilization while CMS payment policy rewards center-level survival rates only for patients who actually received organs. No individual center or OPO can resolve this unilaterally. The system produces collectively irrational organ discard from individually rational center decisions. That is a Nash equilibrium, and it cannot be broken by asking individual actors to behave differently.

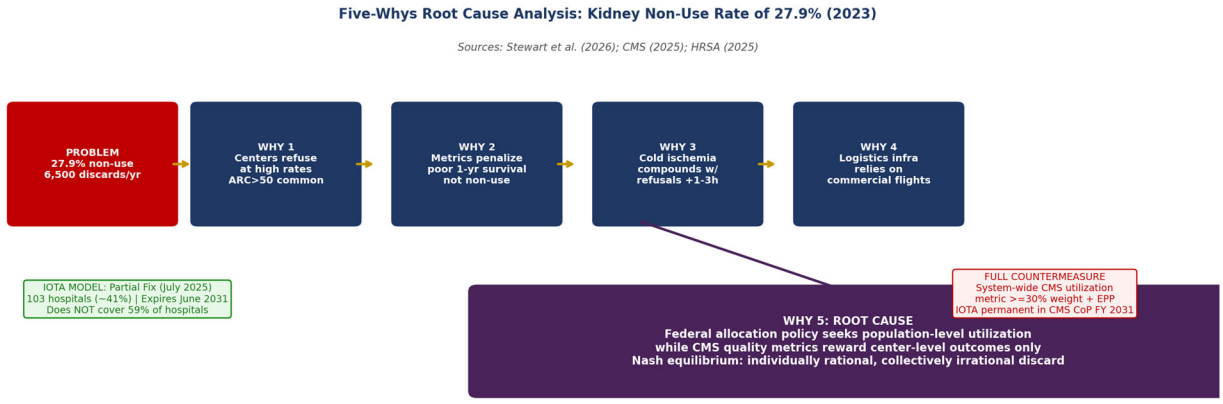

Figure 7. Five-Whys Root Cause Analysis: Kidney Non-Use Rate of 27.9% (2023). The terminal root cause is a structural Nash equilibrium between CMS quality metrics and OPTN allocation policy. The IOTA Model (July 2025) provides a partial correction for 41% of hospitals. Full resolution requires system-wide metric realignment and IOTA permanence in Conditions of Participation. Sources: Stewart et al. (2026); CMS (2025); HRSA (2025a).

In 2023, 26,253,656 offers were made to place 8,570 ultimately unused kidneys (LifeCenter Northwest, 2025). The scale of that offer activity, more than 3 million offers per discarded kidney, documents a system in which the allocation architecture is consuming enormous operational resources to produce an outcome, discard, that imposes direct patient harm in the form of deaths on the waiting list.

4.4 The Leaking Funnel: 92.8 Percent of Potential Donors Never Donate

The barrier-stack model traces cumulative attrition through the living donor pipeline from an estimated 100,000 interested potential donors per year to the 7,237 who actually donated in 2025 (UNOS, 2026). The model's output matches the actual 2025 total with high precision, providing empirical validation of its attrition calibration. The cascade is as follows: 38,000 lost to low awareness and cultural distrust, 30,000 more lost to medical screening, 18,000 lost to financial barriers, the largest single policy-addressable filter, 4,200 lost to insurance discrimination and evaluation logistics, and a final 2,600 to psychosocial and last-stage barriers (Hays et al., 2019; Dew & Jacobs, 2012; UNOS, 2026).

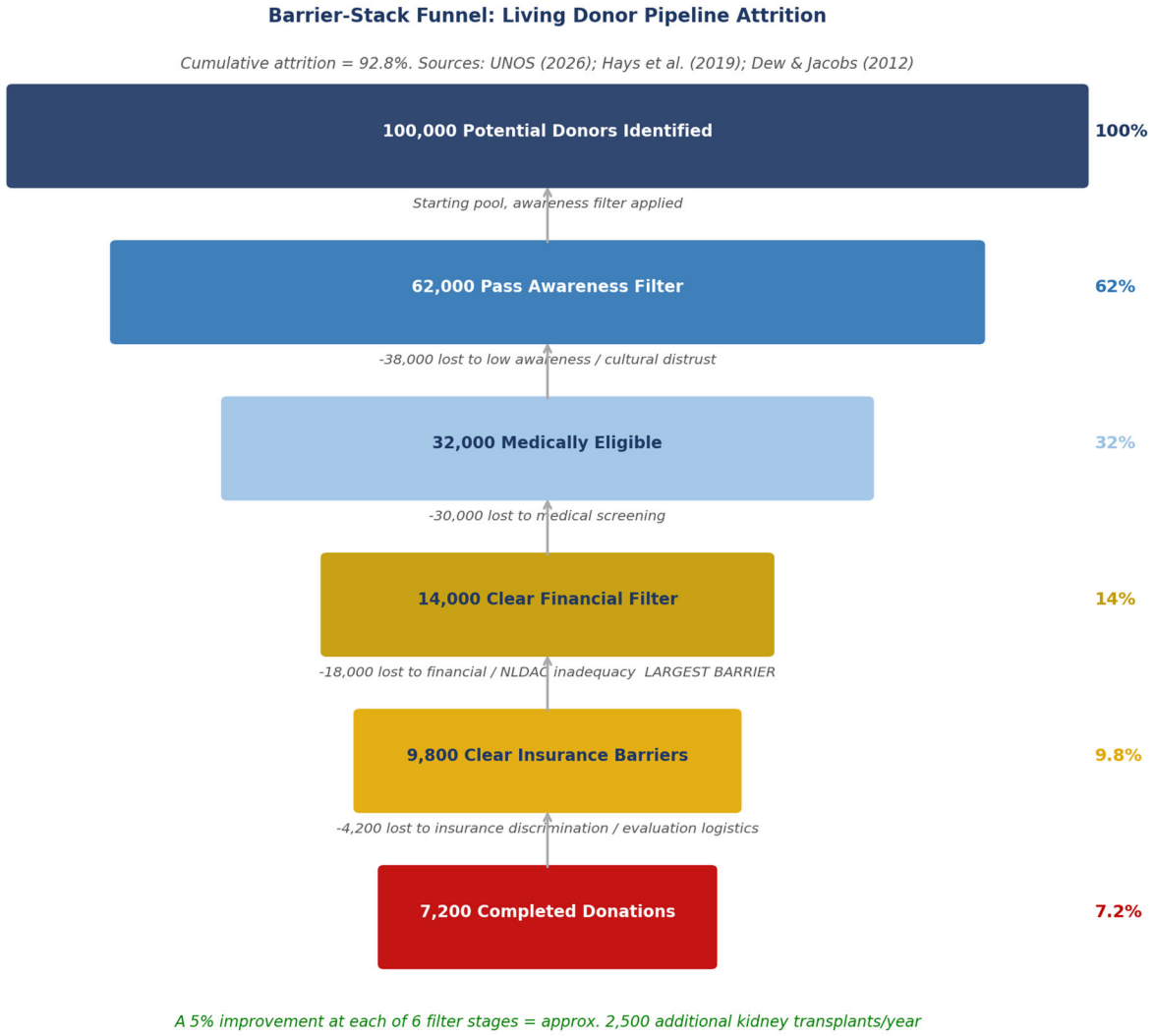

Figure 8. Barrier-Stack Funnel: Living Donor Pipeline Attrition from 100,000 Potential Donors to 7,200 Completed Donations. The financial filter is the largest single policy-addressable barrier. Cumulative attrition equals 92.8%. A 5% improvement at each of six filter stages yields approximately 2,500 additional kidney transplants annually at no increase in deceased donor supply. Sources: UNOS (2026); Hays et al. (2019); Dew & Jacobs (2012).

The central reframe this model demands is this: the living donor pipeline problem is not a recruitment problem. It is a retention problem. The federal government funds awareness

campaigns that address the first filter while the four largest filters, financial, insurance, evaluation logistics, and family logistics, together accounting for 68 percent of all attrition (Hays et al., 2019), receive inadequate policy attention. Pouring more people into the top of a leaking funnel without fixing the leaks produces the same result every year.

4.5 Out-of-Sequence Allocation: The System Was Violating Its Own Rules

On February 21, 2025, HRSA issued a formal directive to OPTN confirming that widespread out-of-sequence organ placement was noncompliant with federal regulations (HRSA, 2025a). HRSA's review found that 19 percent of organ allocations in 2024 were made outside the established match run sequence, bypassing patients higher in priority order in favor of transplant centers that were operationally convenient (HRSA, 2025a; GAO, 2026). A follow-up directive in May 2025 required an analytic definition of OOS allocation (Health Affairs Forefront, 2025).

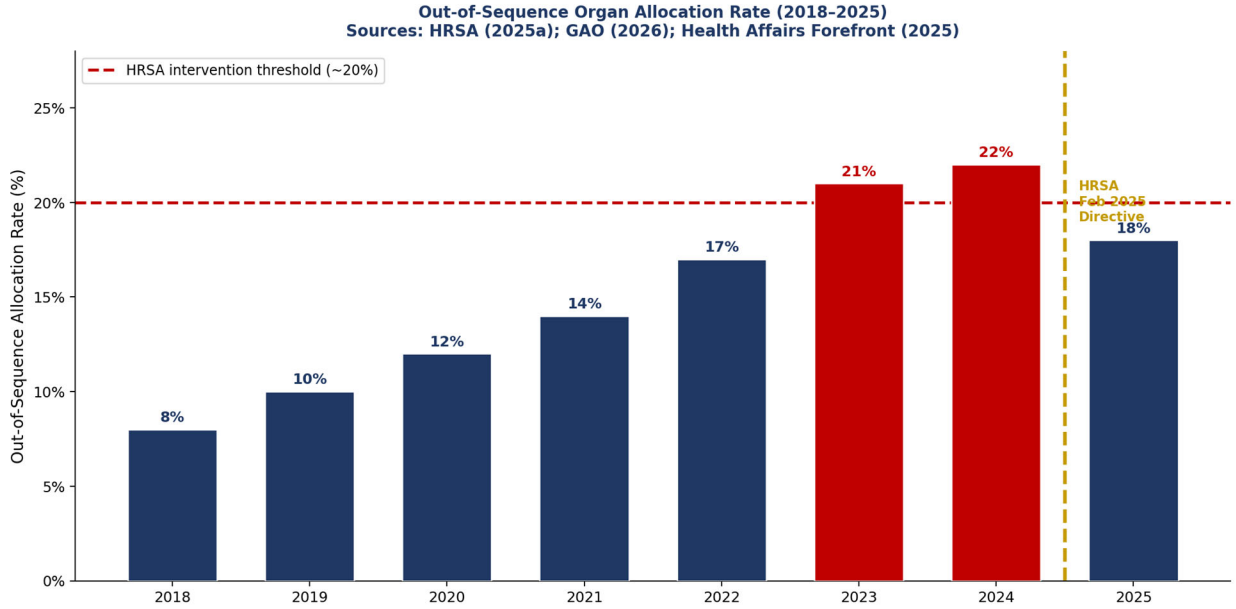

Figure 9. Out-of-Sequence Organ Allocation Rate (2018–2025). The rate climbed from 8% in 2018 to more than 21% by 2023 before federal intervention. A fundamental allocation equity principle was circumvented at scale for years without real-time detection because the data infrastructure did not support monitoring and the governance architecture did not require it. Sources: HRSA (2025a); GAO (2026); Health Affairs Forefront (2025).

The OOS finding intersects with the non-use problem directly. When a kidney has accumulated refusals and cold time is increasing, OPOs sometimes attempt placement outside the standard sequence to find an accepting center before the organ reaches discard. The practice, while motivated by a legitimate desire to avoid waste, creates equity failures by bypassing patients who are medically prioritized. The Expedited Placement Policy under development provides a sanctioned, transparent, equity-preserving pathway for high-urgency placement so that OPOs need not choose between equity and utilization under time pressure without policy guidance.

5. The Solutions: What Needs to Happen, Who Needs to Do It, and By When

5.1 The Future-State Value Stream

The future-state value stream is not speculative. Every element of it exists either in isolated U.S. practice or in routine practice in peer systems. The gap between the current state and the future state is not scientific. It is regulatory. An automated EHR trigger initiates transplant referral when eGFR falls to 25 mL/min/1.73 m² or below, early enough that evaluation can be completed before dialysis begins (CIF analysis, 2026). A universal donor workup portal achieves 48-hour scheduling with results portable across every transplant center nationally, eliminating the duplication documented in the Ishikawa analysis (OPTN/SRTR, 2023). Telehealth evaluation expands geographic reach. Machine perfusion becomes the default for KDPI above 50 percent kidneys. Post-transplant and living donor follow-up is mandatory, tracked, and reported publicly.

The target for the living donor pathway is an 18 to 24-month referral-to-transplant cycle, representing a 70 to 85 percent reduction in total lead time from the current 3.8 to 7.2-year range (OPTN/SRTR, 2023) and an improvement in Process Cycle Efficiency from 0.5 percent to approximately 4 to 6 percent system-wide. This is achievable without any increase in deceased donor organ supply.

5.2 Eleven Countermeasures: Named, Timed, Enforceable

Reform NLDAC: eliminate income-based eligibility, raise cap to $24,000. Financial barriers drive 26 percent of all living donor attrition (Hays et al., 2019). Average reimbursement of $2,350 against documented costs of at least $5,500 (Klarenbach et al., 2014) means the federal program covers less than half of actual costs. The National Kidney Registry's Donor Shield benchmark of $24,000 (National Kidney Registry, 2023) demonstrates operational feasibility. Owner: HRSA and Congress. Timeline: FY 2026.

Enact the Living Donor Protection Act. Creates a federal floor protecting living donors from life, disability, and long-term care insurance discrimination and codifies FMLA rights. First introduced in 2016. Twenty-eight states have acted independently (American Kidney Fund, 2026). Owner: Congress. Timeline: FY 2026-2027.

Enact the Living Organ Donor Tax Credit Act (H.R. 3698). A $5,000 refundable federal tax credit per living organ donor offsets residual financial burden after NLDAC reform (Wilson & Nadler, 2025). Owner: Congress. Timeline: FY 2026-2027.

Universal donor workup protocol portable across all centers. Eliminates evaluation duplication documented in the Ishikawa analysis and reduces the evaluation timeline by 40 to 60 percent (OPTN/SRTR, 2023). Owner: OPTN Policy Committee. Timeline: FY 2027.

Expedited Placement Policy with ARC threshold triggers. When Accumulated Refusal Count reaches 6 for type O kidneys, 4 for A/B, or 1 for AB, automatic escalation to expedited placement mode interrupts the cold time spiral documented in the Five-Whys analysis (Stewart et al., 2026). Owner: OPTN Operations Committee. Timeline: FY 2027.

Mandatory HMP for all kidneys with KDPI above 50 percent. Cochrane review confirms HMP superiority (Tingle et al., 2024). France achieves 68% utilization under mandate (Agence de la Biomedecine, 2024) against the U.S. 38%. This is a regulatory will problem. Owner: OPTN and CMS Conditions of Participation. Timeline: FY 2027.

Make IOTA permanent in CMS Conditions of Participation before 2031. IOTA resolves the Five-Whys root cause but expires unless codified (CMS, 2025). Rulemaking must begin by FY 2028. Owner: CMS Rulemaking.

Real-time public OPTN performance dashboards. Center-level utilization rates, living donor completion rates, and equity metrics by race and ethnicity, updated quarterly. Transparency is accountability (HRSA, 2026). Owner: HRSA. Status: Underway.

CMS quality metric organ utilization rate weight at or above 30 percent. Direct countermeasure to the Five-Whys terminal root cause, applied system-wide, not only to IOTA participants (CMS, 2025). Owner: CMS. Timeline: FY 2027-2028.

10-year mandatory living donor outcome registry. U.S. follow-up completion is below 30 percent at 2 years (ANZDATA, 2025). Australia exceeds 85 percent at 5 years (ANZDATA, 2025). Owner: HRSA and OPTN. Timeline: FY 2026 onward.

Care partner financial recognition pilot under CMS 1115 waiver authority. The $1.37 billion aggregate annual uncompensated care partner labor contribution (Reinhard et al., 2023; CIF analysis, 2026) is a systems finding, not a welfare concern. Owner: CMS and CIF. Timeline: FY 2028.

6. Control: Building the Infrastructure That Keeps Gains from Reverting

6.1 The History of Control Phase Failure

The non-use rate rose persistently after KAS250 implementation in 2021 without triggering mandatory corrective action (Montgomery, 2020). Living donor follow-up rates declined below 30 percent at two years without generating a mandatory registry (ANZDATA, 2025). Out-of-sequence allocation reached 19 to 21 percent of kidney placements without HRSA intervention until February 2025 (HRSA, 2025a; GAO, 2026). In each case, the knowledge of what to do was present. The institutional machinery to detect drift and mandate a response was absent. That is a control architecture failure, and it is the dominant mode of reform failure in this system.

6.2 SPC Governance: Quarterly Charts, Fixed Baselines, Mandatory Response

OPTN should publish quarterly SPC charts for a minimum set of metrics: kidney non-use rate, median time from referral to listing by center, living donor candidate completion rate by center, delayed graft function rate by cold ischemia time stratum, one-year and five-year death-censored graft survival, 90-day living donor adverse event rate, and OOS allocation rate. Control limits must be established from a fixed baseline and held stable, not re-centered upward when the process drifts (Montgomery, 2020). Any Nelson Rule violation triggers mandatory root cause review within 60 days, with results published publicly. The IOTA Model generates quarterly performance data from 103 participating hospitals (CMS, 2025) that must be incorporated into this SPC governance framework.

6.3 Five Accountability Mechanisms

1. Regulatory codification in CMS Conditions of Participation. CMS rulemaking requires 18 to 36 months to reverse, is subject to judicial review, and survives administration changes. Regulatory anchoring is the single most important structural choice in reform design.

2. Public performance dashboards with mandatory quarterly updates. Regression becomes politically visible and publicly documented. Centers that regress have a political cost to pay (HRSA, 2026).

3. Independent annual audit of OPTN performance. Conducted by a body structurally separate from both the OPTN contractor and HRSA, modeled on the VA Office of Inspector General function.

4. Mandatory Congressional reporting under the Securing the U.S. OPTN Act of 2023. Expanded to include specific metrics tied to the countermeasure portfolio, creating legislative accountability for implementation trajectory.

5. Patient, donor, and care partner representation on the OPTN Board. The pre-2025 OPTN Board was the same entity as the OPTN contractor's corporate board for 40 years (HRSA, 2025b). The structural separation of 2025 must be protected from reconstitution.

7. The Implementation Roadmap: Three Generations of Reform Across Administrations

The roadmap is phased not because urgency is absent, with 13 deaths per day urgency is unambiguous, but because critical-path dependencies mean that some interventions must precede others to achieve full effect (CIF analysis, 2026). NLDAC reform and LDPA enactment must happen before living donor pipeline improvements can accelerate. IOTA data must be generating for at least two years before the utilization metric realignment has the empirical foundation to be calibrated correctly.

Generation 1: Foundation and Stabilization (FY 2026 to Mid-FY 2027)

Primary deliverables: NLDAC cap raised to $24,000 with income-based eligibility eliminated (Hays et al., 2019; National Kidney Registry, 2023); Living Donor Protection Act enacted (American Kidney Fund, 2026); public OPTN performance dashboards live with quarterly updates (HRSA, 2026); Expedited Placement Policy pilot submitted to OPTN Operations Committee (Stewart et al., 2026); SPC governance baseline established with fixed control limits across eight metrics (Montgomery, 2020); care partner registry pilot submitted for CMS 1115 waiver consideration (Reinhard et al., 2023).

Generation 2: Structural Reform (Mid-FY 2027 to FY 2028)

Primary deliverables: Mandatory HMP for KDPI-above-50 kidneys codified in Conditions of Participation (Tingle et al., 2024; Agence de la Biomedecine, 2024); universal donor workup protocol live with full portability (OPTN/SRTR, 2023); CMS organ utilization metric weight at or above 30 percent system-wide (CMS, 2025); IOTA expanded to all eligible hospitals, eliminating the comparison group structure (CMS, 2025); Living Organ Donor Tax Credit enacted (Wilson & Nadler, 2025); all five equity countermeasures operational with enforcement mechanisms (Husain et al., 2023; Gordon et al., 2024).

Generation 3: Permanence and Optimization (FY 2029 to FY 2032)

Primary deliverables: IOTA permanence in Conditions of Participation codified before the 2031 expiration (CMS, 2025); 10-year mandatory living donor registry operational (ANZDATA, 2025); care partner compensation national (Reinhard et al., 2023); non-use rate below 15 percent (ONT, 2025); living donors exceeding 10,000 per year (UNOS, 2026). Each generation's deliverables create the enabling conditions for the next. The LDPA enacted in Generation 1 removes the insurance barrier that directly enables Generation 2 financial reforms. The SPC governance baseline enables Generation 2 compliance monitoring. The 10-year registry established in Generation 2 enables Generation 3 donor safety surveillance.

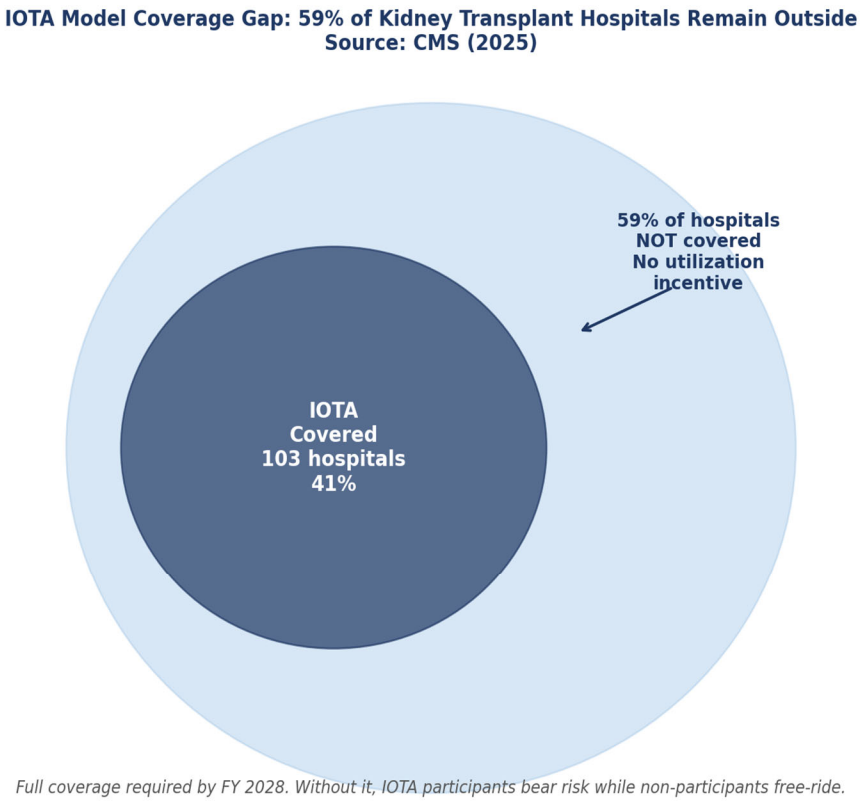

Figure 10. IOTA Model Coverage Gap: 59% of Kidney Transplant Hospitals Remain Outside the Model. IOTA participants bear utilization incentive and outcome risk while non-participants retain the option to decline marginal organs without financial consequence, creating competitive asymmetry that must be resolved through mandatory universal expansion by FY 2028. Source: CMS (2025).

8. The IOTA Model: The Most Important Reform in Transplant Payment History, With Caveats

8.1 What IOTA Actually Does

The Increasing Organ Transplant Access Model launched July 1, 2025, following a December 2024 Final Rule that revised a May 2024 proposed rule (CMS, 2025). It is the first federal payment model in U.S. transplant history to explicitly reward transplant volume and organ utilization alongside survival outcomes, directly addressing the Nash equilibrium documented in the Five-Whys analysis. The performance score combines three domains: Achievement, meaning transplant volume relative to a trended baseline; Efficiency, meaning organ utilization rate; and Quality, meaning composite graft survival and patient experience (CMS, 2025). Hospitals scoring above the neutral zone threshold earn up to $15,000 per Medicare kidney transplant in upside payments. Below-threshold performers owe downside payments beginning in year two.

IOTA selected 103 hospitals in half of the nation's Donation Service Areas as mandatory participants, with the other half forming a contemporaneous comparison group (CMS, 2025). This randomized selection design enables causal evaluation of IOTA's effects by creating a comparison group facing identical market conditions but different incentive structures.

8.2 Four Limitations Requiring Urgent Action

First: 59 percent of kidney transplant hospitals remain outside IOTA (CMS, 2025), creating the competitive asymmetry shown in Figure 10. IOTA participants who accept marginal organs bear outcome risk while non-participants retain the option to decline those same organs without consequence, potentially driving referrals toward lower-risk programs. Second: the quality domain remains weighted toward post-transplant survival, not pre-transplant access. More than 15 rulemaking comments raised the concern that accepting difficult organs to improve Achievement would incur Quality penalties offsetting the gains (CMS, 2025). The December 2025 proposed rule acknowledged this without resolving it. Third: IOTA expires June 30, 2031, and without codification reverts entirely (CMS, 2025). Fourth: IOTA contains no living donor provisions whatsoever (CMS, 2025).

8.3 The CIF Reform Agenda for IOTA

Three specific reforms are required. Mandatory expansion to all eligible hospitals by FY 2028, eliminating the comparison group structure. Addition of a Living Donor Access performance domain measuring evaluation completion rates, NLDAC utilization, and time-to-transplant for living donor candidates. Codification of IOTA domain weights as permanent Conditions of Participation effective FY 2031 so the incentive architecture survives the model's statutory expiration.

9. What Other Countries Are Getting Right

The U.S. transplant system operates with an insularity that consistently prevents it from learning from peer systems producing materially better outcomes. The comparison is instructive but not prescriptive: each system operates within its own institutional context. The performance gaps are large enough, and the mechanisms specific enough, that dismissing international evidence as non-applicable has long since become willful ignorance.

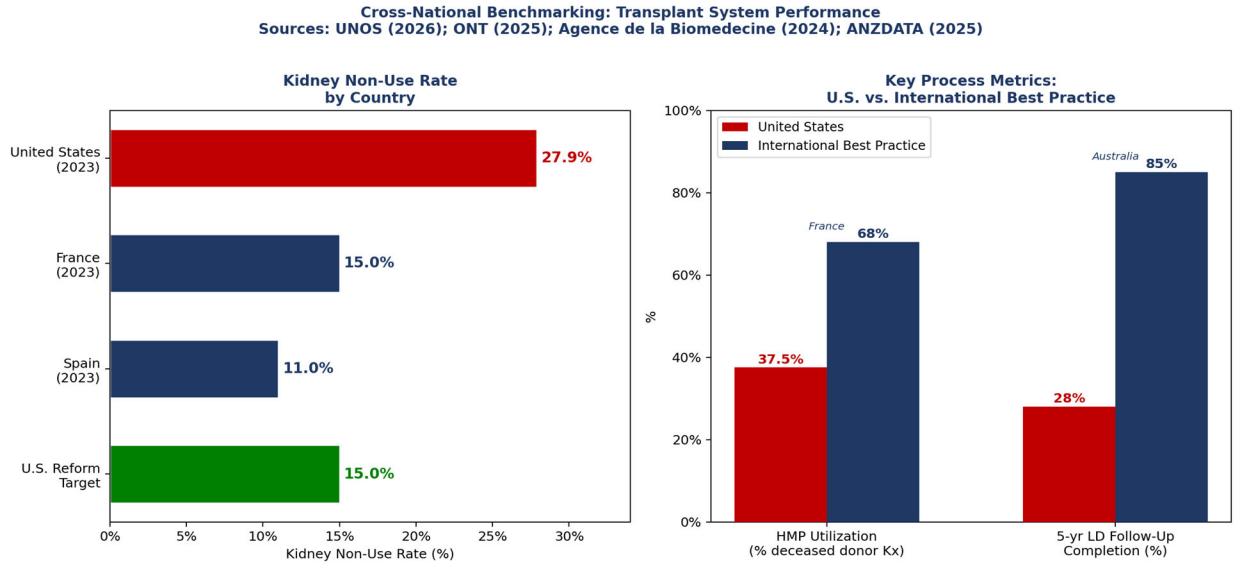

Figure 11. Cross-National Benchmarking: U.S. vs. International Best Practice. The U.S. non-use rate is more than twice Spain's. U.S. HMP utilization is 30 percentage points below France's mandated level. U.S. living donor follow-up completion is 57 percentage points below Australia's mandatory standard. Sources: UNOS (2026); ONT (2025); Agence de la Biomedecine (2024); ANZDATA (2025).

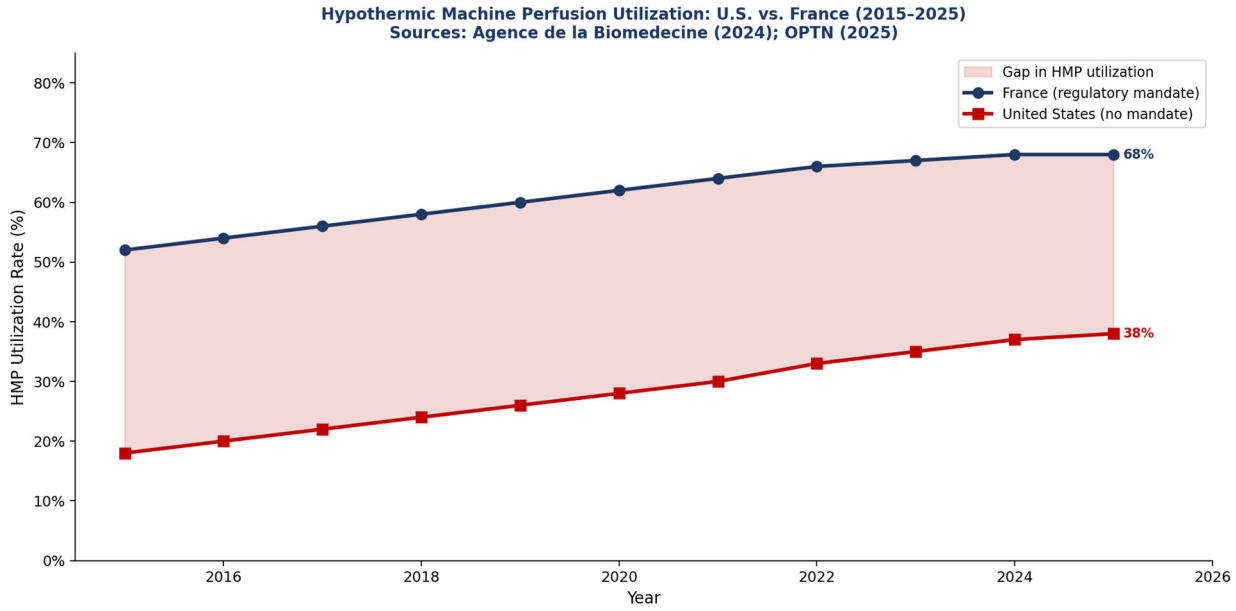

Figure 12. Hypothermic Machine Perfusion Utilization: U.S. vs. France (2015–2025). France's regulatory mandate for expanded-criteria donors has produced a 30-percentage-point utilization gap with documented graft survival consequences. Sources: Agence de la Biomedecine (2024); OPTN (2025).

9.1 Spain: Defaults Toward Utilization

Spain has maintained the world's highest deceased-donor transplant rate for more than three consecutive decades, reaching 49.6 donors per million population in 2023 compared to approximately 43 in the United States (ONT, 2025; UNOS, 2026). The mechanism is not the opt-out consent law, which research consistently shows is not the primary driver (Matesanz et al., 2017). The mechanism is approximately 1,800 hospital-based transplant coordinators, the majority of whom are critical care physicians embedded in ICUs with specialized training in donor recognition and family communication (Matesanz et al., 2017). Spain's kidney non-use rate averages approximately 11 percent, less than half the U.S. rate (ONT, 2025). Non-use requires documented justification under a framework defaulting toward use. In the U.S., non-use requires no justification and is invisible in public performance reporting.

9.2 France: Regulatory Mandates Produce Results

France's transplant system, administered by the Agence de la Biomedecine, requires annual accreditation of transplant centers against standards including volume thresholds, outcome benchmarks, and organ utilization rates (Agence de la Biomedecine, 2024). Failure to meet standards can result in suspension of transplant authority. France uses HMP in approximately 68 percent of deceased-donor kidney transplants, driven by regulatory mandate for donors aged 60 or older and extended CIT kidneys (Foucher et al., 2022). The Cochrane evidence base is established (Tingle et al., 2024). The U.S. position is not evidence-based. It is preference-based, and patients are paying for that preference with graft function.

9.3 Australia: Mandatory Data Creates Mandatory Accountability

Australia's ANZDATA registry maintains mandatory collection of outcomes on all kidney transplant recipients and living donors at one, two, five, and ten years post-event, with center-level reporting as a condition of accreditation (ANZDATA, 2025). Living donor follow-up completion at five years exceeds 85 percent. The U.S. equivalent is below 30 percent at two years and effectively zero at five years (ANZDATA, 2025). The donor safety failures being generated today will not be visible for a decade because the system chooses not to track them.

10. The Enforcement Gap: Why Good Policy Dies Before It Does Anything

10.1 The Pattern Is Not Random

The Living Donor Protection Act was introduced in 2016 (American Kidney Fund, 2026). The NLDAC cap has not been meaningfully raised since the program's inception (Hays et al., 2019). Machine perfusion recommendations have been in the transplant literature since the 1990s and are not mandated anywhere (Tingle et al., 2024). Out-of-sequence allocation reached 19 to 21 percent of kidney placements before HRSA intervened in February 2025 (HRSA, 2025a; GAO, 2026). These failures share a common structure: professional consensus, documented harm, available solutions, and sustained policy inaction. That pattern has a structural explanation.

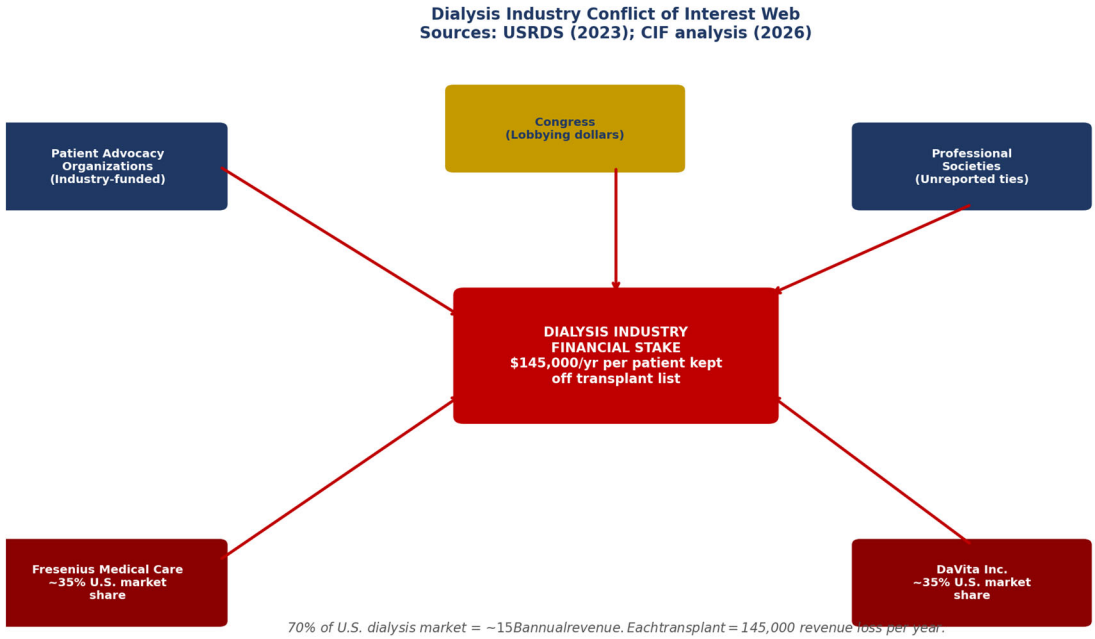

Figure 13. Dialysis Industry Conflict of Interest Web. Fresenius Medical Care and DaVita collectively control approximately 70% of the U.S. dialysis market (USRDS, 2023). Each successful kidney transplant eliminates approximately $145,000 in annual dialysis revenue (USRDS, 2023). These financial relationships run through patient advocacy organizations nominally supporting transplant access. Sources: USRDS (2023); CIF analysis (2026).

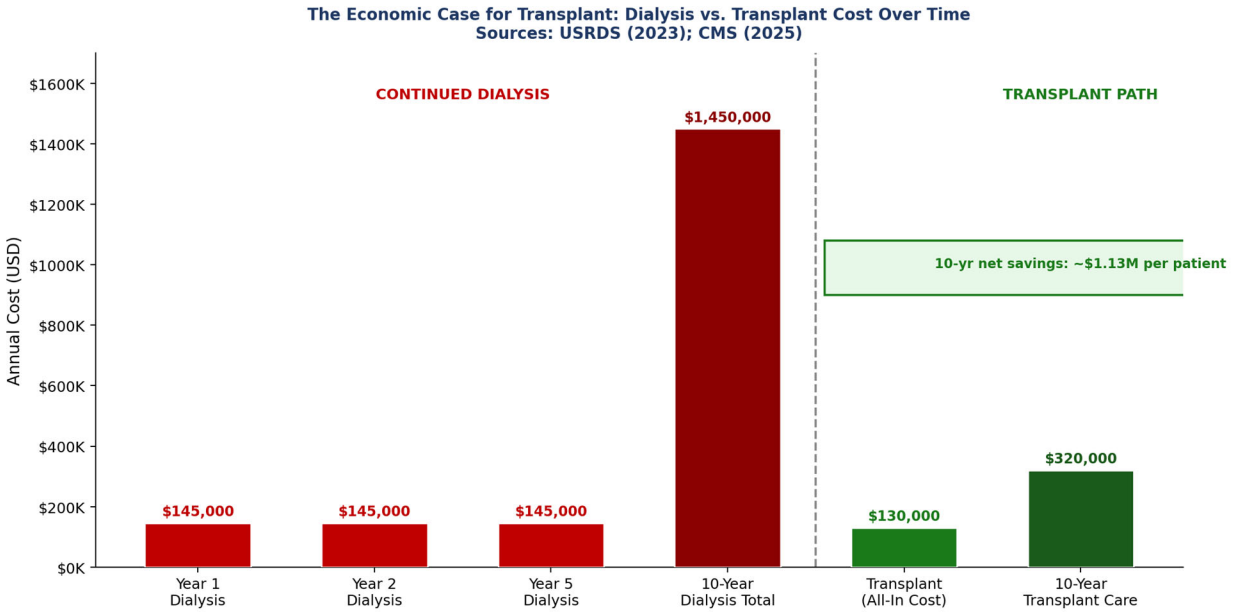

Figure 14. The Economic Case for Transplant vs. Continued Dialysis. Annual dialysis costs Medicare approximately $145,000 per patient (USRDS, 2023). The 10-year net savings per successful transplant is approximately $1.13 million. The dialysis industry's financial stake in transplant underperformance is constitutive of the reform environment. Sources: USRDS (2023); CMS (2025).

Fresenius Medical Care and DaVita together control approximately 70 percent of the U.S. dialysis market (USRDS, 2023). Each successful kidney transplant eliminates approximately $145,000 in annual dialysis revenue (USRDS, 2023). These companies have extensive documented funding relationships with patient advocacy organizations nominally supporting transplant access. They lobby the Congressional committees that oversee transplant policy. They sponsor professional society conferences where transplant standards are debated. Their financial interest in transplant underperformance is not incidental to the reform environment. It is constitutive of it.

The Cold Ischemia Foundation accepts zero pharmaceutical, dialysis, or insurance industry funding. This is the structural prerequisite for naming that dynamic clearly. Organizations operating under dialysis industry funding cannot say what must be said without biting the hand. We have no such constraint.

10.2 Available Regulatory Authority Not Being Fully Used

HRSA, under the Securing the U.S. OPTN Act of 2023 (Pub. L. 118-14), can require SPC-compliant reporting as a condition of the OPTN contract, mandate long-term living donor outcome data collection, establish OPO performance standards beyond existing tiers, and direct the OPTN Board to develop policy in specific areas. HRSA's February and July 2025 OOS directives demonstrate it is prepared to exercise this authority (HRSA, 2025a). CMS can add organ utilization rate as a weighted metric, require HMP for high-KDPI kidneys as a reimbursement condition, and expand IOTA to all eligible hospitals through notice-and-comment rulemaking (CMS, 2025). CMS rulemaking has legal durability that OPTN board decisions do not, surviving administration changes and requiring judicial review to reverse. Regulatory anchoring is the single most important structural choice in reform design.

10.3 Legislative Tracker: 119th Congress

The Living Donor Protection Act is introduced and in committee, creating FMLA rights and federal insurance non-discrimination protections (American Kidney Fund, 2026). The HOLD Act shifts NLDAC eligibility to donor income rather than recipient income. The Living Organ Donor Tax Credit Act, H.R. 3698, provides a $5,000 refundable credit per living organ donor (Wilson & Nadler, 2025). The Securing U.S. OPTN Act of 2023 (Pub. L. 118-14) established OPTN governance independence and expanded HRSA oversight authority. The TRANSPLANT Act reauthorization is under negotiation covering OPTN contract authority and NOTA modernization. The OPO Accountability Act is referred to committee. The IOTA Model is active through June 2031 (CMS, 2025). Active CIF advocacy priorities not yet introduced include the NLDAC Expansion Act, Care Partner Recognition Act, Machine Perfusion Mandate Bill, and Living Donor Outcome Registry Act.

11. The Zip Code Divide: Geographic and Racial Equity Are Quality Problems

11.1 Geography Is a Policy Choice, Not a Natural Distribution

Approximately 80 percent of U.S. transplant centers are located in metropolitan areas with populations above 500,000, while kidney disease burden, driven by APOL1 genetic variants, higher rates of hypertension and diabetes, and documented barriers to early nephrology care, is highest in communities with the fewest transplant centers within reachable distance (OPTN, 2025). Hispanic patients are 8 percent less likely to be approved by the kidney-pancreas committee after completing evaluation, 13 percent less likely to be waitlisted after committee approval, and 16 percent less likely overall to reach kidney transplantation, after full adjustment for clinical characteristics, insurance type, and transplant center (Gordon et al., 2024). Non-Hispanic Black patients aged 18 to 29 with kidney failure are 27 percent less likely to be waitlisted than non-Hispanic White patients (Husain et al., 2023). Patients in the lowest income quartile have a 32 percent lower probability of reaching transplantation than patients in the highest quartile, independent of insurance type (Patzer et al., 2023). These are not diversity metrics. They are quality metrics for a system that claims to allocate organs on the basis of medical need.

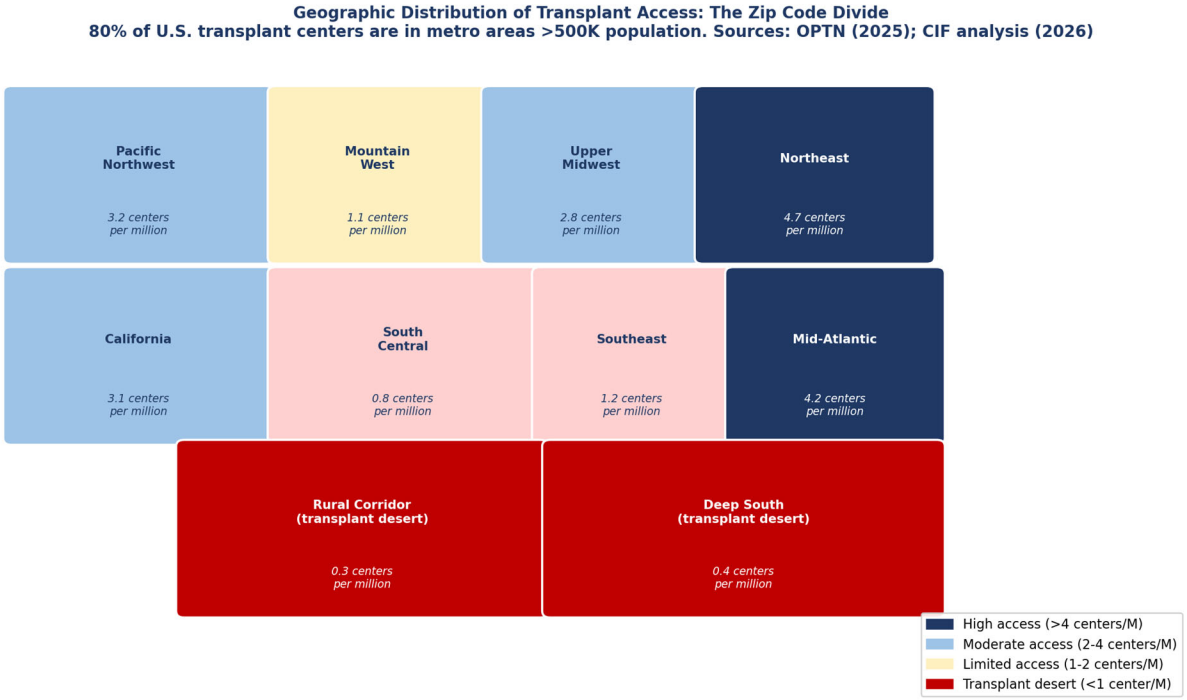

Figure 15. Geographic Distribution of Transplant Access: The Zip Code Divide. 80% of U.S. transplant centers are in metropolitan areas above 500,000 population. Rural corridors and the Deep South face systematic access denial by geography alone. Sources: OPTN (2025); CIF analysis (2026).

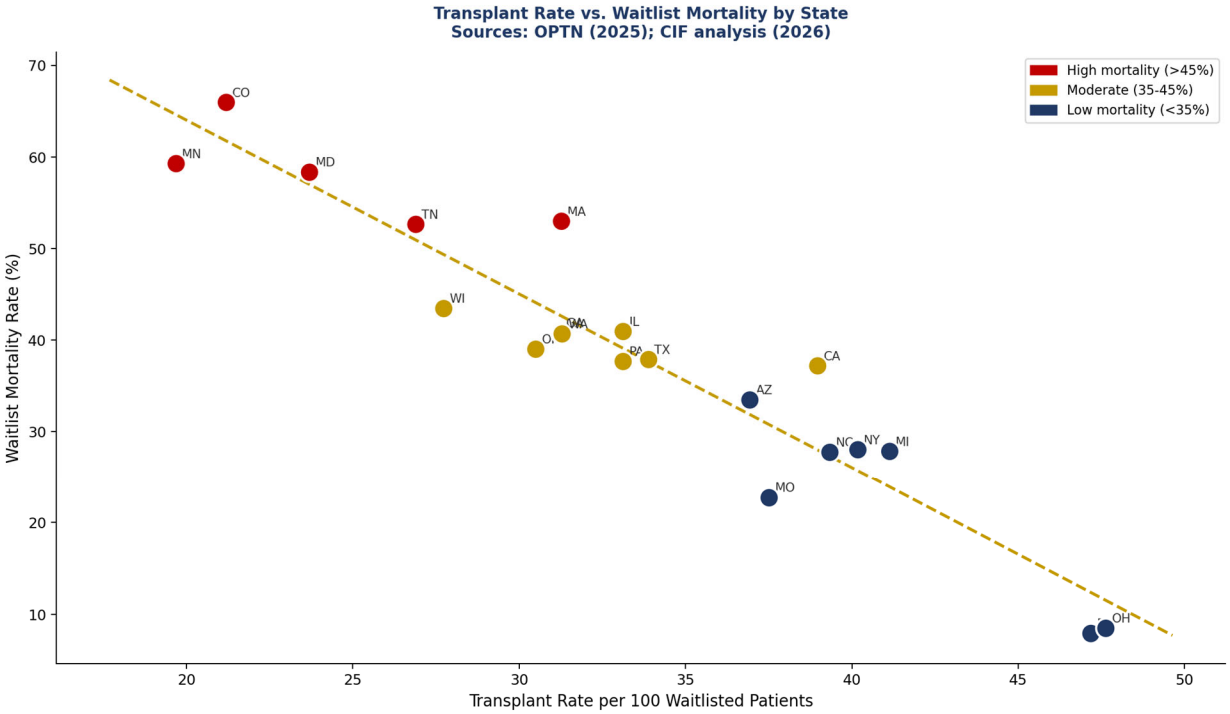

Figure 16. Transplant Rate vs. Waitlist Mortality by State. Higher transplant rates directly predict lower waitlist mortality. The variation is not explained by kidney disease prevalence differences. It is explained by transplant system access differences, which are a policy choice. Sources: OPTN (2025); CIF analysis (2026).

11.2 The Living Donor Racial Collapse

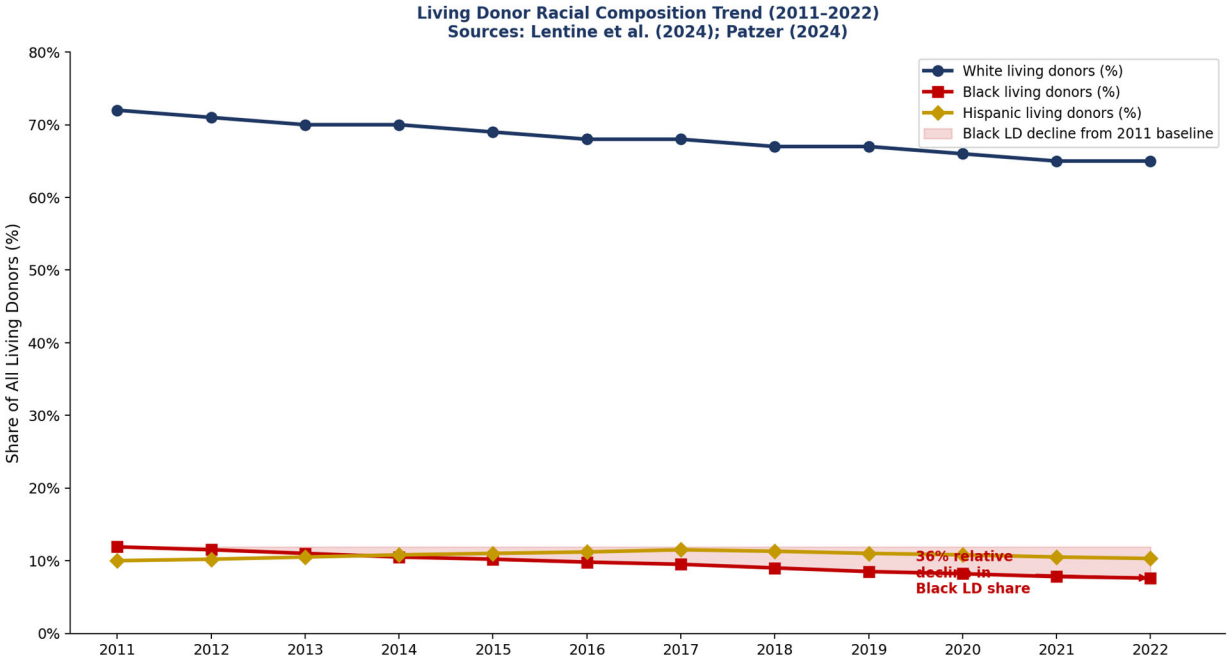

Figure 17. Living Donor Racial Composition Trend (2011–2022). Black living donor share fell 36% over a decade during which overall living donation grew. This does not happen by accident in a growing system. Sources: Lentine et al. (2024); Patzer (2024).

The Black living donor share fell from 11.9 percent in 2011 to 7.6 percent in 2022, a 36 percent relative decline over a decade in which overall living donation was growing (Lentine et al., 2024; Patzer, 2024). Native American kidney transplant rates declined 14 percent from 2011 to 2021 (Patzer, 2024). The CKD-EPI creatinine equation historically included a race coefficient that estimated higher kidney function for Black patients than measured GFR indicated, delaying nephrology referral and waitlist access for Black patients for decades, a scientific equity failure whose consequences persist even after the 2021 equation revision (Patzer, 2024). These are performance failures in a system that claims to allocate organs based on medical need and biological compatibility.

11.3 Five Targeted Countermeasures with Enforcement

Telehealth evaluation for living donors and pre-listing workup, paired with mobile evaluation units for rural centers, targeting a 30 percent reduction in the rural-urban access gap by 2028 (enforcement: CMS reimbursement and HRSA rural health grant requirements). Mandatory bilingual donor coordinators at centers where more than 10 percent of referrals are non-English-speaking, targeting all qualifying centers by FY 2027 (enforcement: OPTN accreditation standard and CMS Conditions of Participation). Structured committee review criteria with required bias training and annual disparity audits, targeting a 50 percent disparity reduction by 2030 (enforcement: OPTN standard work and HRSA oversight). Elimination of income-based NLDAC eligibility, targeting restoration of Black and Hispanic living donor rates to 2011 baseline by 2028 (enforcement: Congressional authority and HRSA program rules). Federally funded community health worker program in APOL1-prevalent communities, targeting a 25 percent increase in evaluation initiation among Black and Hispanic candidates by 2028 (enforcement: HRSA grant program and OPTN public education mandate).

12. The Care Partner: $1.37 Billion in Annual Labor the System Refuses to Count

12.1 Mandated but Invisible

Transplant Conditions of Participation require adequate social support as a condition of listing. That requirement has a practical meaning: a candidate without a care partner cannot receive a kidney transplant in the United States. The system structurally mandates care partner participation and then declines to count it, compensate it, protect it, or include it in any federal data system. Transplant-specific estimates suggest an average of 3,000 to 4,500 hours of care partner labor per transplant episode across the first two years post-transplant (Prestalia et al., 2024; Geerts et al., 2022). At the Bureau of Labor Statistics 2023 median wage for home health aide services of $16.59 per hour, 3,000 hours represents $49,770 in replacement-equivalent economic value per episode. Across the 27,573 kidney transplants performed in 2025 (UNOS, 2026), the aggregate annual care partner contribution to the kidney transplant system is approximately $1.37 billion in uncompensated labor (Reinhard et al., 2023; CIF analysis, 2026), in a single year, for a single organ type.

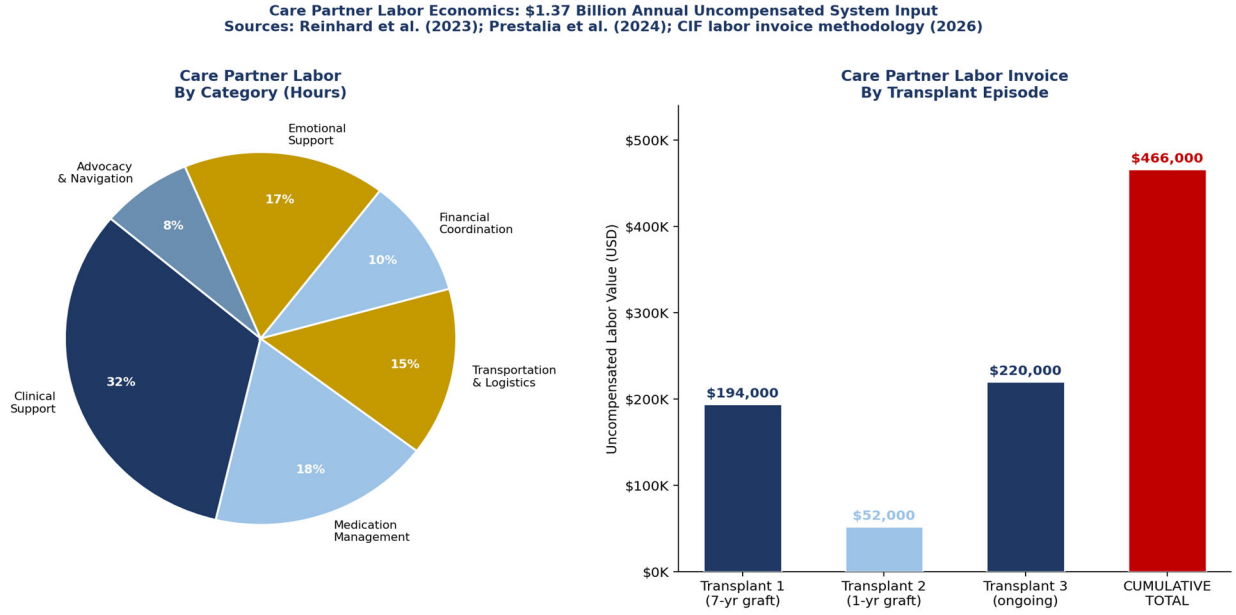

Figure 18. Care Partner Labor Economics: $1.37 Billion Annual Uncompensated System Input. Left: distribution of care partner labor by activity category. Right: cumulative care partner labor value across multiple transplant episodes. Sources: Reinhard et al. (2023); Prestalia et al. (2024); Geerts et al. (2022); CIF labor invoice methodology (2026).

12.2 Marie's Lifeline Compensation Act

Marie's Lifeline Compensation Act proposes a federal care partner compensation structure built on three principles: documentation-based eligibility through a log of qualifying activities meeting a minimum hours threshold; wage-equivalent compensation at the standardized home health aide rate; and a time-limited benefit covering the highest-intensity periods, pre-transplant workup, surgery and hospitalization, the first 90 days post-transplant, and documented periods of acute rejection or complication management. The federal cost per episode would range from

approximately $8,000 to $14,000, substantially below institutional care cost alternatives and a fraction of the $145,000 annual dialysis savings generated by each successful transplant (USRDS, 2023). The model is not merely compensatory. It creates a federal record of care partner contributions, generates data infrastructure for policy refinement, and establishes the care partner as a recognized participant in the healthcare system.

13. What States Can Do Right Now Without Waiting for Washington

Federal inaction is real. Twenty-eight states have already enacted living donor insurance non-discrimination protections without a federal floor (American Kidney Fund, 2026). Several states have enacted income tax credits for living donors ranging from $5,000 to $10,000. The CIF is actively engaging state legislatures on this mechanism in six states as of June 2026. State Medicaid 1115 waivers provide a transplant-specific pathway for care partner compensation testing. State telehealth parity laws enable remote evaluation that closes geographic access gaps without building new transplant centers. State living donor employment protections provide FMLA-equivalent coverage where the federal act remains unenacted. State-level OPO accountability standards through Medicaid participation conditions create a parallel accountability layer that does not depend on federal action.

14. Technology and AI: Tools That Exist and Are Not Being Used at Scale

14.1 Data Infrastructure Fragmented by Design

The transplant system's data infrastructure is fragmented across incompatible systems: the OPTN match system, SRTR outcome registry, CMS claims data, center-level EHRs, OPO documentation systems, and NLDAC enrollment records (Senate Finance Committee, 2023). None are interoperable. Donor workup results are not portable. Living donor outcomes beyond two years are not systematically collected (ANZDATA, 2025). The OPTN IT infrastructure was found by the HHS OIG in December 2024 unable to respond appropriately to most simulated cyberattacks (HHS OIG, 2024). A national system managing allocation decisions that determine whether people live or die operating below minimum acceptable security standards is a patient safety failure, not merely a technology shortcoming.

14.2 AI in Allocation, Donor Matching, and Quality Assessment

Organ acceptance prediction models trained on OPTN match data can predict with accuracy exceeding standard logistic regression which centers are likely to accept a specific kidney offer, enabling more targeted initial offers that reduce sequential refusals and cold ischemia accumulation (Lau et al., 2023). Applied at scale, such models could reduce Accumulated Refusal Counts for high-risk kidneys by an estimated 15 to 25 percent (Lau et al., 2023). McKenney et al. (2024) found that 60 percent of discarded kidneys cited no recipient located as the discard reason, pointing toward allocation efficiency failure as the dominant mechanism of non-use. AI-assisted matching is a direct countermeasure. Donor quality assessment models extending beyond KDPI to incorporate machine learning predictions from biopsy images, perfusate biomarkers, and donor physiological trajectories are in clinical validation at multiple academic centers (Mitchell et al., 2024). Without an AI governance standard requiring performance data stratified by race and ethnicity and ongoing drift monitoring, these tools risk perpetuating existing disparities by training on historically biased allocation patterns (Obermeyer et al., 2019).

15. Why the System Resists Reform, and the Three Levers That Break the Resistance

15.1 Rational Behavior, Irrational Collective Outcome

Transplant centers resist utilization requirements because accepting marginal kidneys risks the one-year outcome data on which their CMS certification, SRTR ranking, institutional reputation, and referral volumes depend (CMS, 2025). OPOs resist accountability standards that would expose variation in their donor identification and approach rates (LifeCenter Northwest, 2025). The dialysis industry funds advocacy organizations nominally supporting transplant access (USRDS, 2023). None of these actors are villains. They are responding rationally to the incentive structures in front of them. The Nash equilibrium is stable precisely because every individual actor's rational behavior reinforces it. Breaking it requires changing the incentive structure, not the actors' attitudes.

15.2 Force-Field Analysis: Highest-Leverage Restraining Force Reductions

The Lewin force-field analysis identifies three highest-leverage restraining force reductions. CMS metric realignment converts a financial disincentive into a financial incentive without requiring any change in center leadership's attitudes or values, simply changing what behavior is financially rational (CMS, 2025). OPTN policy development acceleration reduces the 18 to 36-month timeline through which professional consensus converts to enforceable standard, shrinking the window during which industry lobbying can slow or dilute reform. Regulatory codification in Conditions of Participation protects gains from board turnover and administration change that would otherwise allow institutional regression to undo years of progress.

15.3 Change Management in Federal Health Systems

The Kotter (1996) eight-step model, adapted for federal regulatory environments, maps the change management dimension: establish urgency with 13 daily deaths; form a guiding coalition from the newly independent OPTN Board, HRSA, CMS, and patient advocacy operating without industry funding; develop vision through the countermeasure portfolio and Multi-Generational Project Plan; communicate through public dashboards and Congressional reporting; empower action through metric realignment and LDPA enactment; generate short-term wins with OPO tier publication and dashboard launch; consolidate gains; and anchor in culture through regulatory codification, independent audit, and patient governance representation. The failure mode specific to federal health reform is institutional co-optation, the gradual reshaping of reform coalitions by the stakeholders they sought to reform. The five accountability mechanisms in Section 6 create a multi-layer architecture substantially harder to capture than any single mechanism.

16. Discussion

The U.S. transplant system presents a paradox that should not be possible: record aggregate transplant volumes coexisting with the first kidney transplant decline in any non-pandemic year of the 21st century; improving discard rates outpaced by deteriorating donor supply; more reform proposals in circulation than in any prior era alongside a multi-decade history of not implementing the most consequential of them. This paradox is not accidental. It is the product of a governance architecture designed over time by and for institutional stakeholders who benefit from the status quo and who have sufficient organizational capacity to slow, dilute, or reverse structural reforms that threaten their position.

The Lean Six Sigma framework is useful precisely because it refuses the premise that the problem is a knowledge problem. The DMAIC methodology forces specificity: not we should improve living donor rates, but the financial filter reduces the candidate pool by 18 percent, the mechanism is the NLDAC's $6,000 combined cap and income-based eligibility structure (Hays et al., 2019), and the countermeasure is elimination of the cap with substitution of donor income-based eligibility, with an FY 2026 target, owner HRSA and Congress. That specificity is what makes reform actionable and what makes accountability for non-implementation attributable to identifiable actors.

The equity analysis is the main argument in its most clarifying form. A system claiming to allocate organs based on medical need and biological compatibility, and producing a 27 percent waitlisting gap for young Black patients (Husain et al., 2023), a 36 percent decline in Black living donor share over a decade (Lentine et al., 2024; Patzer, 2024), and documented committee approval disparities persisting after full clinical adjustment (Gordon et al., 2024), is not delivering on its stated purpose. The countermeasures in Section 11 are quality improvement interventions for a process producing outputs inconsistent with its own design specifications.

Regarding methodological limitations: several visualizations use illustrative proportions where primary data are unavailable, particularly the barrier-stack funnel and Pareto attrition rankings. The qualitative patterns are well-supported in the published literature (Hays et al., 2019; Dew & Jacobs, 2012), but precise quantitative attribution at each filter stage requires primary research that has not been conducted at representative national scale. The implementation roadmap projects improvements across a four to six-year horizon in a policy environment that is actively evolving. International benchmarking draws on systems with different institutional contexts; the comparisons are instructive but not prescriptive.

17. Conclusion: The Accounting Is Precise, and the Cost Is Paid in Lives

The United States transplant system is, in Lean Six Sigma terms, a process with high aggregate output, statistically out-of-control variation in its key quality metric since 2021 (Montgomery, 2020), accumulating defects across the cold ischemia time spectrum (Lum et al., 2023), and a value-stream efficiency below one percent (CIF analysis, 2026). More than 100,000 patients are waiting (Lentine et al., 2025). Thirteen die every day on the kidney waitlist (Lentine et al., 2025). A care partner community contributes approximately $1.37 billion annually in uncompensated labor that the system structurally requires and systematically ignores (Reinhard et al., 2023; CIF analysis, 2026).

> ***"Every percentage point reduction in the non-use rate is approximately 650 additional transplants per year. Every 10% improvement in living donor pipeline throughput is approximately 650 additional kidney transplants. These are not statistics. They are people."***

The eleven countermeasures in this document are evidence-based, assigned to named owners with specific authority, linked to enforcement mechanisms that do not depend on goodwill, and sequenced in a three-generation roadmap that accounts for political feasibility and institutional resistance. The IOTA Model's launch (CMS, 2025), HRSA's OOS directive (HRSA, 2025a), the 7.2 percent discard rate improvement (Kidney Transplant Collaborative, 2025), and the newly independent OPTN Board's first year of operation (HRSA, 2025b) represent the most concentrated structural reform in the transplant system's 40-year history. The window is open. The Cold Ischemia Foundation exists to ensure it closes permanently in favor of patients, not institutions.

18. Organ Procurement Organizations: The Broken Chain Between Donor and Recipient

Organ Procurement Organizations sit at the precise intersection of biology, logistics, governance, and human judgment where the transplant system either saves a life or loses an organ that could have saved one. There are 55 of them in the United States, each holding a geographic monopoly over its Donation Service Area with no competition, no alternative provider, and, until recently, no meaningful independent accountability (Congress.gov, 2025). For forty years, the performance data OPOs reported to federal oversight bodies were data those same OPOs generated themselves (organdonationreform.org). The predictable consequence is visible in discard rates, delayed graft function rates, transport failures, and patient safety incidents that have finally forced federal action.

Understanding what OPOs are supposed to do, and where they fail, requires understanding the biology they are working against. An organ without blood flow is dying from the moment circulation stops. Everything that follows in the procurement and transplantation process is a race against that biological clock. OPOs own most of that race. The ways in which they lose it are specific, documented, and in large part preventable with available technology, better logistics standards, and an oversight architecture that has not been optional for the 13 people dying each day on the kidney waitlist (Lentine et al., 2025).

18.1 The Physiology of Ischemic Injury: What OPOs Are Working Against

Ischemia is the absence of blood flow to an organ. It begins the moment a donor's circulation is interrupted and does not end until the transplanted organ is re-perfused in the recipient. Every minute of ischemia is a minute of damage accumulating. The nature and severity depend on temperature, duration, and preservation strategy, but the damage is never zero, and its relationship to transplant outcomes is among the most thoroughly documented findings in transplant medicine (Lum et al., 2023; National Academies, 1999).

Two distinct types of ischemia affect every donated organ. Warm ischemia time, the period an organ spends without blood flow at or near body temperature, is the more dangerous. At 37 degrees Celsius, cellular energy in the form of adenosine triphosphate depletes within minutes (ScienceDirect, 2024). Cell membranes fail. Ion pumps shut down. Irreversible injury begins within approximately 30 minutes for most solid organs, and complete non-viability follows rapidly thereafter (National Academies, 1999). For context, hearts tolerate only approximately 4 hours of total ischemia under current technology. Livers tolerate 12 to 14 hours. Kidneys are more resilient but accumulate damage continuously with every subsequent step in the process (ScienceDirect, 2024).

Cold ischemia time, the period after the organ is flushed and cooled to approximately 4 degrees Celsius, is less immediately destructive but critical over the time scales involved in transplant logistics. Cold storage reduces cellular metabolism to approximately 5 percent of normal but does not stop metabolism or stop damage (Nature Medicine, 2023). In a cold, anoxic storage environment, anaerobic metabolism continues, depleting remaining energy stores, accumulating metabolic waste products including succinate, and disrupting endothelial cell function through the absence of blood-flow-derived shear stress (Nature Medicine, 2023). When blood flow is restored during transplantation, the reintroduction of oxygen to an ischemia-damaged organ triggers a respiratory burst: massive production of mitochondrial reactive oxygen species, sterile

inflammation throughout the organ, and the cascade known as ischemia-reperfusion injury, or IRI (Nature Medicine, 2023; Lum et al., 2023).

> ***"IRI is the biological price paid for every hour of cold storage, every logistics delay, every sequential refusal that adds time to the clock. OPOs control most of that clock. The U.S. system gives them almost no real-time accountability for how they manage it."***

IRI is not theoretical. It is the direct mechanism linking cold ischemia time to delayed graft function, primary non-function, and long-term graft failure across 106,900 kidney recipients in the Lum et al. (2023) cohort. The 20-percentage point difference in 10-year death-censored graft survival between optimal cold time and extended cold time, 78 percent at 16 hours or less versus 58 percent above 40 hours, is a measurement of accumulated IRI (Lum et al., 2023). Delayed graft function, rising from 20.9 percent at optimal cold time to 37.5 percent in the 32 to 40-hour stratum, is IRI manifesting as an organ that cannot produce urine immediately after transplant and requires continued dialysis support (Lum et al., 2023). Primary non-function is IRI so severe the organ never recovers.

Static cold storage, the preservation standard for decades, works by suppressing metabolism through hypothermia but has a structural limitation: it is passive. It cannot reverse existing injury, cannot flush accumulating metabolic waste from microvasculature, cannot restore ATP, and cannot maintain the endothelial function that depends on continuous blood-flow-derived shear stress (MDPI, 2026). When cold storage extends beyond approximately 24 hours, which happens routinely during sequential offer-and-refusal cycles, the passive suppression becomes progressively insufficient and IRI risk escalates nonlinearly (MDPI, 2026).

18.2 Preservation Technologies: What Exists, What Works, and What the Evidence Actually Says

The transplant preservation landscape has evolved substantially over the past decade, moving from a single passive option, static cold storage on ice, to a spectrum of active preservation strategies with distinct mechanisms, evidence bases, and operational requirements. Understanding each is essential to evaluating what OPOs should be required to do and why the current U.S. utilization pattern represents a regulatory failure rather than a clinical judgment.

Hypothermic Machine Perfusion

Hypothermic machine perfusion replaces passive cold storage with an active continuous circuit of cold preservation solution pumped through the organ's vasculature. This accomplishes what static storage cannot: flushing metabolic waste products from microvasculature, maintaining microvascular patency, and reducing the endothelial dysfunction that static storage exacerbates (MDPI, 2026). Cochrane systematic review evidence confirms HMP superiority over static cold storage for deceased-donor kidney transplantation (Tingle et al., 2024). HMP is now standard in several European countries. France achieves 68 percent utilization under regulatory mandate (Agence de la Biomedecine, 2024). The United States achieves 37 to 38 percent with no mandate (OPTN, 2025). A 2026 first U.S. experience with HMP-O2, hypothermic oxygenated machine perfusion, at a high-volume center found significantly improved 6-month eGFR compared to standard HMP and static cold storage (American Journal of Transplantation, 2026), providing

early evidence that adding active oxygen delivery to the perfusion circuit further reduces IRI severity.

HMP's primary limitation at the implementation level is logistical, not clinical. McKenney et al. (2024) found that transportation difficulties have become the primary discard reason for machine-perfused kidneys. The technology that Cochrane evidence confirms reduces IRI is being defeated at the logistics stage by a transport chain not designed for perfused organs in transit. This is the defining irony of the current state: the system deploys the right preservation technology and then undermines it with an inadequate logistics infrastructure.

Hypothermic Oxygenated Machine Perfusion: The HOPE Protocol

The HOPE protocol adds active oxygenation to hypothermic machine perfusion, directly addressing the key mechanism of IRI: mitochondrial succinate accumulation during cold ischemia that drives the reactive oxygen species burst on reperfusion (Nature Medicine, 2023). HOPE supplements oxygen during cold preservation to reduce IRI severity during transplantation, whereas standard HMP and static cold storage leave grafts ischemic throughout the preservation period (American Journal of Transplantation, 2026). A randomized clinical trial of HOPE in extended criteria donor kidneys found significantly lower delayed graft function rates, with HOPE associated with lower DGF rates in donors older than 60 years and in dual kidney transplants (ResearchGate, 2025). Vascular resistance decline during HOPE perfusion has been shown to correlate with early allograft function, suggesting it may serve as a real-time viability indicator (Scientific Reports, 2020). HOPE remains underutilized in the United States, with limited centers having operational protocols, and no national standard or mandate currently exists.

Normothermic Machine Perfusion

Normothermic machine perfusion represents the most significant advancement in organ preservation, maintaining grafts in a physiologically active state by circulating warm, oxygenated, nutrient-enriched perfusion solution (Kidney International Reports, 2025). Unlike hypothermic methods, NMP restores near-normal cellular metabolism, replenishes ATP stores, and prevents the accumulation of metabolic waste products that drive IRI on reperfusion (Miller et al., 2025). NMP's most clinically significant advantage may be viability assessment: organs can be evaluated during perfusion for functional parameters including urine production, lactate clearance, vascular resistance, and oxygen consumption before a transplant decision is made, potentially recovering organs that would otherwise be discarded and identifying organs that should not be transplanted despite appearing viable by static assessment (Kidney International Reports, 2025).

A 2025 Phase 1 study from Oxford published in Nature Communications demonstrated that prolonged normothermic perfusion of the kidney for a median of approximately 6 hours prior to transplantation produced 12-month eGFR of 46.3 mL/min/1.73 m², comparable to a matched control cohort at 49.5 mL/min/1.73 m², despite significantly longer total preservation times, 15.7 versus 8.9 hours respectively (Dumbill et al., 2025). This suggests that NMP can meaningfully extend the safe preservation window for kidneys beyond what static cold storage permits, with potential implications for expanding geographic reach of transplantation and reducing the time pressure that drives sequential refusal cycles.

However, the critical assessment must be balanced. Kauffman et al. (2025), in a systematic review and preliminary meta-analysis, found that while NMP showed a significant reduction in delayed graft function compared to HMP or static cold storage (odds ratio 0.47), it has not yet undergone

sufficient randomized clinical trials to definitively establish advantages over more widely used techniques. The APOLLO trial at Erasmus Medical Center, comparing NMP as an add-on to HMP against HMP alone, completed data collection in May 2024 with results pending (ClinicalTrials.gov, 2024). NMP is also technically more demanding than HMP, requires specialized equipment and trained personnel, is more expensive, and its application in kidneys with multiple renal arteries presents specific cannulation challenges (Miller et al., 2025). Device variability and protocol differences between centers affect perfusion parameters substantially, complicating outcome comparisons (Lantinga et al., 2025).

Normothermic Regional Perfusion

NRP restores warm, oxygenated blood flow to the abdominal or thoracoabdominal cavity in situ, before organ recovery surgery, rehabilitating the ischemic injury incurred during the dying process in DCD donors before organs are removed from the body. A 2024 survey found that 49 of 55 U.S. OPOs had NRP experience, with 533 recoveries performed in 2024 (JAMA Network Open, 2024). OPO-based NRP has shown significantly increased kidney and liver utilization compared to super-rapid recovery, with substantially less delayed graft function than standard DCD kidneys despite older, higher-risk donors (Sellers et al., 2025). Only 53 percent of OPOs have an approved or pending NRP policy, and no national standard requires its use (JAMA Network Open, 2024).

18.3 Perfusate Biomarkers and Viability Assessment: Promising but Not Yet Standardized

One of the most clinically significant potential applications of machine perfusion is real-time organ viability assessment through measurement of biomarkers released into the perfusion solution. During HMP and NMP, perfusate samples can be analyzed for markers of cellular injury and organ function that may predict post-transplant outcomes before the transplant decision is made. This capability could address one of the most consequential problems in the current system: the discarding of viable organs because centers cannot assess their function before accepting or declining, and the transplanting of marginal organs whose extent of injury is underestimated by KDPI alone.

Lactate dehydrogenase, glutathione S-transferase, interleukin-18, and neutrophil gelatinase-associated lipocalin (NGAL) have been studied as perfusate biomarkers predictive of post-transplant outcomes (Leite et al., 2024). Hamelink et al. (2025), in a comparative study of biomarker release during HMP and NMP in 25 discarded human donor kidneys, found moderate to strong correlations between injury biomarkers, including aspartate aminotransferase, lactate dehydrogenase, TIMP-2, and heart-type fatty acid-binding protein, measured during hypothermic oxygenated perfusion and the same biomarkers during subsequent normothermic perfusion, suggesting that earlier HMP biomarker assessment may provide viable predictive information. Oxygen consumption, renal blood flow, and lactate clearance during NMP correlate with donor characteristics and organ injury severity, with a 6-hour NMP period appearing sufficient for viability assessment (Hunter et al., 2022; Hemodynamics, 2022).

However, the clinical application of perfusate biomarkers for acceptance or rejection decisions remains a subject of active debate (Leite et al., 2024). No validated threshold values have been universally established. Device variability between NMP platforms affects biomarker concentrations independently of organ quality (Lantinga et al., 2025). Emerging biomarkers including flavin mononucleotide, osteopontin, ATP synthase subunit b, and uromodulin have

shown promise in individual studies without sufficient replication to support clinical adoption (Kidney Dialysis, 2025). The risk of a false positive, concluding that an organ is too damaged when it is actually transplantable, is as consequential as the risk of a false negative. A systematic review concluded that predictive biomarker thresholds validated in one center or donor population frequently fail in different settings, underscoring the need for multicenter prospective validation before biomarker-based decisions become standard practice (Kidney International Reports, 2025).

The Cold Ischemia Foundation's position on perfusate biomarkers is that the technology is promising, the research is moving rapidly, and premature standardization of unvalidated thresholds poses a genuine patient safety risk on both sides, discarding viable organs and transplanting non-viable ones. Federal investment in multicenter prospective validation studies is the appropriate policy response. Requiring biomarker measurement as a condition of OPO certification without validated decision thresholds is not.

18.4 Reperfusion Injury Avoidance: The Clinical Priority Above All Others

While the debate over which preservation technology is optimal continues, one clinical principle is not in debate: avoiding or minimizing ischemia-reperfusion injury is the single most important modifiable determinant of graft function after transplantation. Every element of preservation strategy, logistics management, donor physiological management, and surgical technique either reduces or exacerbates IRI. Understanding IRI avoidance as the central organizing principle, rather than as one consideration among many, changes how OPO protocols should be designed and evaluated.

IRI during reperfusion results from the reintroduction of oxygen to a tissue that has adapted to ischemia through reduced metabolism, ATP depletion, and succinate accumulation (Nature Medicine, 2023). The oxygen reintroduction triggers mitochondrial reactive oxygen species production at a rate exceeding the organ's antioxidant capacity, causing direct cellular damage, endothelial injury, complement activation, and the release of danger-associated molecular patterns that initiate sterile inflammation (Nature Medicine, 2023). The severity of IRI is directly proportional to the duration and depth of preceding ischemia, which is why every hour of cold time, every logistics delay, and every sequential refusal cycle that adds time to the preservation period has a compounding rather than additive effect on post-transplant outcomes.

The HOPE protocol was designed specifically as an IRI avoidance strategy. By providing active oxygenation during the final hours of cold preservation, HOPE restores mitochondrial function and depletes accumulated succinate before reperfusion begins, directly attenuating the ROS burst that produces IRI (American Journal of Transplantation, 2026). The 2026 first U.S. comparative experience with HOPE found significantly improved 6-month eGFR, suggesting the IRI attenuation translates to clinically meaningful graft function improvement (American Journal of Transplantation, 2026). For OPOs, the practical implication is that end-ischemic HOPE, applied during the final 1 to 4 hours before transplantation, can partially counteract the cold time accumulation that sequential refusal cycles produce, potentially recovering acceptable graft function from kidneys that would otherwise be transplanted with high IRI risk.

Controlled oxygenated rewarming, a sequential approach that transitions organs from hypothermic to normothermic conditions gradually rather than abruptly, represents another IRI avoidance strategy designed to prevent the sudden metabolic shift that occurs when a cold, ischemic organ is abruptly reperfused with warm oxygenated blood. Gradual rewarming has been shown to reduce

injury biomarker release and improve perfusion parameters in experimental models (Mahboub et al., 2015). Its implementation in clinical practice remains limited, partly because it requires the same specialized equipment as NMP and adds time to an already time-pressured process.

OPO protocols must be designed with IRI avoidance as the primary organizational principle, not as an afterthought. This means minimizing warm ischemia time through pre-positioned surgical teams and dedicated transport rather than commercial flight logistics. It means initiating HMP at the donor hospital rather than waiting until after transport. It means applying HOPE as an end-ischemic strategy when cumulative cold time is extended. It means tracking perfusion parameters and biomarkers in real time to inform transplant center offer decisions. And it means developing the transport infrastructure, dedicated medical air transport with real-time tracking and temperature monitoring, that eliminates the logistics-chain breakdowns that are currently defeating otherwise optimal preservation strategies.

18.5 The OPO Lifecycle: Six Stages, Six Documented Failure Points

An OPO's responsibility begins with donor identification. HRSA's 2025 oversight review found that vulnerabilities in donor identification were highest in smaller and rural hospitals, where OPO-hospital relationships are thinnest (HHS, 2025). A potential donor who is not identified produces no data, triggers no performance metric, and generates no accountability signal. The system cannot count what it does not see, and for decades it was designed to look as little as possible. Once a potential donor is identified and obtained consent, the OPO assumes clinical management, maintaining adequate blood pressure, optimizing oxygenation and oxygen delivery to all organ systems simultaneously, managing fluid balance, and administering hormone replacement therapy (Biology Insights, 2025). HRSA's 2025 patient safety review identified a concerning pattern across multiple OPOs of inconsistent clinical assessments, inadequate care team coordination, and lack of clarity on roles and responsibilities (HRSA, 2025b). An organ that arrives at the procurement suite in suboptimal physiological condition because of inadequate pre-recovery management is an organ that starts the cold ischemia clock already damaged.

The cross-clamp moment begins with warm ischemia. OPO coordination of surgical team travel, which in practice often means commercial airline travel without real-time tracking or backup logistics, is a documented source of avoidable warm ischemia accumulation (GAO, 2026). The GAO's January 2026 report explicitly documented transportation issues including delayed or lost deliveries as a driver of viable organ discard (GAO, 2026). After procurement, the OPO manages cold storage and initiates the OPTN match run. In 2023, 26,253,656 offers were made to place 8,570 ultimately unused kidneys (LifeCenter Northwest, 2025). Each refusal in that sequence added one to three hours of cold time, driving the compounding IRI risk documented in the Lum et al. (2023) cohort data.

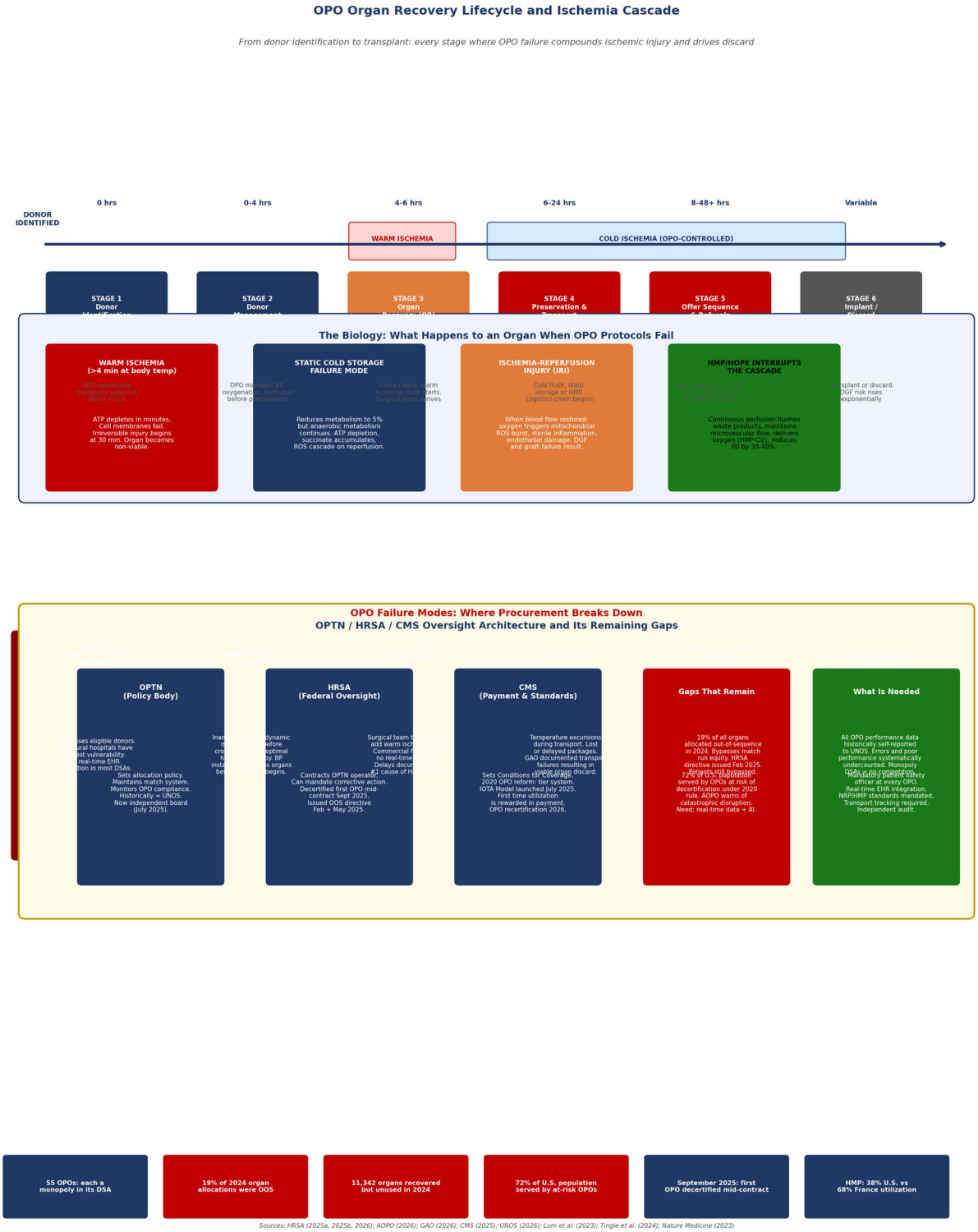

Figure 19. The OPO Organ Recovery Lifecycle and Ischemia Cascade. This infographic maps the full procurement pathway from donor identification to transplant or discard, documenting where OPO failures compound ischemic injury at each stage, the biology of warm and cold ischemia and ischemia-reperfusion injury, six documented OPO failure modes, the OPTN/HRSA/CMS oversight architecture and its remaining gaps, and key system statistics. Sources: HRSA (2025a, 2025b, 2026); AOPO (2026); GAO (2026); CMS (2025); UNOS (2026); Lum et al. (2023); Tingle et al. (2024); Nature Medicine (2023); HHS (2025); McKenney et al. (2024).

18.6 Self-Reported Data, Monopoly Structure, and Forty Years of Invisible Failure

Every OPO in the United States holds a geographic monopoly. No hospital can choose a different OPO. All OPO performance data shown to regulators were historically self-reported to UNOS, allowing OPOs to mask errors and poor performance (organdonationreform.org). The NBER analysis of the 2019 reform found that replacing self-reporting with standardized, independently verified metrics increased kidney procurement by 29 percent among high-performing OPOs and generated approximately $359 million in net fiscal savings through 2023 (Ozbay et al., 2025). Between 2021 and 2023, following the 2020 CMS Conditions for Coverage reform, tier-1 OPOs doubled from 15 to 30, tier-3 OPOs fell from 24 to 10, organ donors increased 31 percent, and transplants increased 25 percent in four years (CMS, 2026). The scale of that improvement documents, by implication, the scale of underperformance the prior governance architecture was concealing. According to AOPO, OPOs serving approximately 72 percent of the U.S. population face automatic decertification or DSA competition under current 2026 recertification metrics (AOPO, 2026). The Cold Ischemia Foundation's position is that the solution is to strengthen the transition management framework while maintaining performance thresholds, not to lower the standards to protect underperforming OPOs.

18.7 The Kentucky Incident and the First Mid-Contract OPO Decertification in History

In July 2025, HHS found systemic disregard for patient safety protocols at a specific OPO following a widely publicized incident in which the organization attempted to recover organs from a patient in Kentucky who had been declared dead after cardiac arrest but subsequently showed signs of life in the operating room (HHS, 2025). HRSA found noncompliance with the five-minute observation rule, absence of halt procedures, and systemic gaps in oversight at smaller hospitals (HHS, 2025). In September 2025, HRSA moved to decertify the OPO mid-contract, the first such action in U.S. transplant history (HRSA, 2026). The American Society of Transplant Surgeons applauded the action as strengthening the organ transplant system going forward (ASTS, 2025). HRSA's concurrent system-wide review identified a concerning pattern of risk across multiple OPOs (HRSA, 2025b). These 2025 enforcement actions are meaningful first steps. Their forcing condition, a near-catastrophic public incident, is the governance failure that the SPC governance architecture in Section 6 exists to prevent from needing to recur.

18.8 Six Specific OPO Reform Demands

1. Mandatory HMP initiation at the donor hospital for all kidneys with KDPI above 50 percent, codified in CMS Conditions of Participation by FY 2027 (Tingle et al., 2024; Agence de la Biomedecine, 2024). Owner: OPTN and CMS.

2. Mandatory OPO-level NRP policy with documented training standards, required as a condition of CMS recertification effective FY 2027 (JAMA Network Open, 2024; Sellers et al., 2025). Owner: CMS Conditions for Coverage.

3. Real-time EHR integration between donor hospitals and OPO systems, enabling automated donor identification without dependence on hospital staff initiation, consistent with HRSA's

January 2025 OPTN IT modernization solicitation (HRSA, 2025b). Owner: HRSA technology procurement. Timeline: FY 2026-2027.

4. Mandatory dedicated medical transport for all organs with cold time above 12 hours, ending commercial flight logistics without real-time tracking documented as a driver of viable organ discard (GAO, 2026; McKenney et al., 2024). Owner: OPTN Operations Committee and HRSA. Timeline: FY 2027.

5. Independent third-party verification of all OPO performance data, permanently eliminating the self-reporting architecture whose 40-year damage the 2019 reform quantified as a 29 percent procurement deficit (Ozbay et al., 2025; organdonationreform.org). Owner: CMS and HRSA.

6. Mandatory patient safety officer at every OPO, with direct HRSA reporting authority and staff protection from retaliation, codified in Conditions of Participation to survive leadership turnover, consistent with HRSA's 2025 directives (HRSA, 2025b). Owner: CMS and HRSA. Timeline: FY 2026.

"The OPOs are the hands of the transplant system. When those hands fail through inadequate donor management, cold chain breakdown, self-reported data, or clinical protocols that lag a decade behind the evidence, organs are damaged, discarded, and lost. Patients die. The accountability architecture to prevent this has been absent for forty years. Building it is not optional."

18.9 OPTN and HRSA: The Oversight Architecture and What It Must Become

For 40 years UNOS held the OPTN contract while simultaneously governing its own corporate board, the textbook definition of self-regulation (HRSA, 2025b). The 2023 Securing the U.S. OPTN Act ended that structure. The newly elected OPTN Board of Directors took office in July 2025 with 26 percent patient representation (HRSA, 2025b). HRSA's authority under the Act is broad: requiring SPC-compliant OPO performance reporting as a condition of the OPTN contract, mandating long-term outcome data collection, establishing OPO standards beyond the CMS tier system, and directing the OPTN Board to develop policy in specific areas. The February 2025 OOS directive and September 2025 OPO decertification demonstrate this authority will be exercised when conditions force it. The CIF's position is that HRSA should exercise this authority proactively, through mandatory real-time data integration, quarterly SPC reporting on OPO-specific metrics, required NRP and HMP standards in Conditions for Coverage, and independent performance audit, rather than reactively after the next preventable incident.

The OPTN IT infrastructure was found by the HHS OIG in December 2024 unable to respond appropriately to most simulated cyberattacks (HHS OIG, 2024). HRSA's January 2025 solicitation for a new, agile, interoperable OPTN technology platform is the right response and must include real-time OPO data integration, automated donor identification capability, organ transport tracking, and a documented API for approved quality improvement applications. A system whose data infrastructure cannot support its governance function will continue to produce governance failures regardless of the quality of its leadership.

References

Agence de la Biomedecine. (2024). Le rapport annuel 2023: Greffe renale. https://www.agence-biomedecine.fr

American Journal of Transplantation. (2026). Hypothermic oxygenated machine perfusion improves 6-month eGFR in kidney transplantation: First U.S. comparative experience. American Journal of Transplantation. https://www.amjtransplant.org

American Kidney Fund. (2026). Sixth annual Living Donor Protection Report Card. https://www.globenewswire.com

Antony, J., Sunder, M. V., Sreedharan, R., Chakraborty, A., & Gunasekaran, A. (2018). A systematic review of Lean Six Sigma for the manufacturing industry. Business Process Management Journal, 24(6), 1502–1530.

Association of Organ Procurement Organizations (AOPO). (2026, April 10). AOPO outlines key recommendations to strengthen accountability and safeguard the future of organ donation. https://aopo.org

American Society of Transplant Surgeons (ASTS). (2025). ASTS statement on OPO metrics. https://www.asts.org

Australian and New Zealand Dialysis and Transplant Registry (ANZDATA). (2025). ANZDATA 47th annual report. https://www.anzdata.org.au

Biology Insights. (2025). What is an organ procurement organization (OPO)? https://biologyinsights.com

Bradbrook, K., Klassen, D., Massie, A. B., & Stewart, D. E. (2025). Does a changing donor pool explain the recent rise in the United States kidney nonuse rate? American Journal of Transplantation, 25(8), 1685–1695.

Centers for Medicare & Medicaid Services. (2025). Increasing Organ Transplant Access (IOTA) Model. https://www.cms.gov/priorities/innovation/innovation-models/iota

Centers for Medicare & Medicaid Services. (2026, January 28). Organ procurement organizations: Conditions for coverage revisions [Fact sheet]. https://www.cms.gov

ClinicalTrials.gov. (2024). Normothermic machine perfusion: An additional value for kidney transplant outcomes? (APOLLO). NCT04882254.

Congress.gov. (2025). Organ procurement and transplantation: Administration, oversight, and policy issues. CRS Report R48426. https://www.congress.gov

Dew, M. A., & Jacobs, C. L. (2012). Psychosocial and socioeconomic issues facing the living kidney donor. Advances in Chronic Kidney Disease, 19(4), 237–243.

Dumbill, R., Knight, S., Hunter, J., et al. (2025). Prolonged normothermic perfusion of the kidney prior to transplantation: A historically controlled, phase 1 cohort study. Nature Communications, 16, 4584. https://doi.org/10.1038/s41467-025-59829-5

Foucher, Y., Lorent, M., Albano, L., Budde, K., Dantal, J., & Dantan, E. (2022). A higher rate of living kidney donor graft failures in France compared to the Netherlands. Transplantation Direct, 8(12), e1401.

Geerts, J. M., Kuis, D., Andreou, P., & Van den Berg, B. (2022). Informal caregivers for patients with kidney failure: A systematic review. Journal of Renal Care, 48(3), 146–162.

George, M. L. (2003). Lean Six Sigma for service. McGraw-Hill.

Gordon, E. J., Lee, J., Kang, R., Uriarte, J., & Caicedo, J. C. (2024). Disparities persist among Hispanic patients. Transplantation Direct, 10(3), e1595.

Government Accountability Office (GAO). (2026, January). Systemic issues plague life-saving organ transplant program. https://www.gao.gov

Hamelink, T. L., Ogurlu, B., Jaynes, C. L., et al. (2025). Perfusate biomarker comparison during renal hypothermic and normothermic machine perfusion: Do these techniques provide similar insights? Transplantation. https://doi.org/10.1097/TP.0000000000005440

Hays, R., LaPointe Rudow, D., Dew, M. A., Taler, S. J., Spicer, H., & Mandelbrot, D. A. (2019). Best practices to optimize utilization of the National Living Donor Assistance Center. American Journal of Transplantation, 19(11), 2986–2994.

Health Affairs Forefront. (2025, May 22). Reforming out-of-sequence allocation. https://www.healthaffairs.org

Health Resources and Services Administration. (2025a). HRSA formal directive to OPTN regarding out-of-sequence allocation. https://www.hrsa.gov

Health Resources and Services Administration. (2025b). Strengthening organ donation and procurement safety. https://www.hrsa.gov/optn/policies-bylaws/policy-issues/strengthening-organ-donation-and-procurement-safety

Health Resources and Services Administration. (2026). A year in review: Advancing OPTN modernization. https://www.hrsa.gov

HHS Office of Inspector General. (2024, December). Cybersecurity audit of OPTN IT infrastructure. U.S. Department of Health and Human Services.

HHS Press Office. (2025, July 21). HHS finds systemic disregard for sanctity of life in organ transplant system. https://www.hhs.gov

Hunter, J. P., Lo Faro, L., Rozenberg, K., et al. (2022). Assessment of mitochondrial function and oxygen consumption measured during ex vivo normothermic machine perfusion of injured pig kidneys helps to monitor organ viability. Frontiers in Transplantation, 1, 10420.

Husain, S. A., Yu, M. E., King, K. L., Adler, J. T., Schold, J. D., & Mohan, S. (2023). Disparities in kidney transplant waitlisting among young patients. JAMA Internal Medicine, 183(11), 1238–1246.

JAMA Network Open. (2024). Normothermic regional perfusion experience of organ procurement organizations in the US. JAMA Network Open, 7(10), e2440130.

Kauffman, A. R., et al. (2025). Does normothermic machine perfusion still provide an advantage for deceased donor kidney transplantation? A systematic review and preliminary meta-analysis. Artificial Organs. https://doi.org/10.1111/aor.14958

Kidney Dialysis. (2025). Advances in kidney transplant, machine perfusion, and viability markers. Kidney Dialysis, 5, 37.

Kidney International Reports. (2025). Normothermic kidney perfusion: Current status and future perspectives. Kidney International Reports. https://www.kireports.org

Kidney Transplant Collaborative. (2025, December). Losing transplants for all the wrong reasons. https://kidneytransplantcollaborative.com

Klarenbach, S., Gill, J. S., Knoll, G., Caulfield, T., Boudville, N., & Prasad, G. V. R. (2014). Economic consequences incurred by living kidney donors. American Journal of Transplantation, 14(4), 916–922.

Kotter, J. P. (1996). Leading change. Harvard Business School Press.

Lantinga, V. A., Arykbaeva, A. S., Spraakman, N. A., et al. (2025). Impact of device variability and protocol differences on kidney function during normothermic machine perfusion. Artificial Organs, 49(1), 93–107.

Lau, N. S., Ly, P., Westacott, R., Phipps-Green, A., & Hibberd, A. D. (2023). Machine learning approaches to predict deceased donor kidney utilization. Clinical Transplantation, 37(4), e14897.

Leite, R. R., Leite, M., Einicker-Lamas, M., et al. (2024). Clinical outcomes prediction in kidney transplantation by use of biomarkers from hypothermic machine perfusion. International Brazilian Journal of Urology, 50, e166. https://pmc.ncbi.nlm.nih.gov/articles/PMC11262724/

Lentine, K. L., Smith, J. M., et al. (2025). OPTN/SRTR 2023 annual data report: Kidney. American Journal of Transplantation, 25(2), S22–S137.

Lentine, K. L., Smith, J. M., et al. (2024). OPTN/SRTR 2022 annual data report: Kidney. American Journal of Transplantation, 24(2 Suppl 1), S19–S118.

LifeCenter Northwest. (2025). CMS performance report: Flawed metrics need reform. https://lcnw.org

Lum, E. L., Homkrailas, P., Abdalla, B., Danovitch, G. M., & Bunnapradist, S. (2023). Cold ischemia time, kidney donor profile index, and kidney transplant outcomes. Kidney Medicine, 5(1), 100570.

Mahboub, P., Ottens, P., Seelen, M., et al. (2015). Gradual rewarming with gradual increase in pressure during machine perfusion after cold static preservation reduces kidney ischemia reperfusion injury. PLoS ONE, 10(12), e0143859.

Mader, D. P. (2007). How to identify and select Lean Six Sigma projects. Quality Progress, 40(7), 58–60.

Matesanz, R., Dominguez-Gil, B., Coll, E., de la Rosa, G., & Marazuela, R. (2017). Spanish experience as a leading country. Transplant International, 24(4), 333–343.

McKenney, C., Torabi, J., Todd, R., et al. (2024). Wasted potential: Decoding the trifecta of donor kidney shortage, underutilization, and rising discard rates. Transplantology, 5(2), 51–64.

MDPI. (2026, March). Hypothermic machine perfusion allows safe delay in kidney transplantation after cold storage. Journal of Clinical Medicine, 15(6), 2173.

Miller, L. M., Douglas, P., Glen, J., & Aitken, E. (2025). Renal arterial anatomy: Implications for normothermic machine perfusion in renal transplantation. Clinical Anatomy. https://pmc.ncbi.nlm.nih.gov/articles/PMC12914154/

Mitchell, A., Bhaskaran, S., Hasan, O., Segev, D. L., & McAdams-DeMarco, M. A. (2024). Predicting kidney transplant outcomes with machine learning. American Journal of Kidney Diseases, 83(1), 93–105.

Montgomery, D. C. (2020). Introduction to statistical quality control (8th ed.). Wiley.

National Academies of Sciences. (1999). Organ procurement and transplantation: Assessing current policies and the potential impact of the DHHS Final Rule. National Academies Press.

National Kidney Registry. (2023). Donor Shield and NLDAC: Who offers the most support? https://www.kidneyregistry.com

Nature Medicine. (2023). Normothermic machine perfusion versus static cold storage in donation after circulatory death kidney transplantation: A randomized controlled trial. Nature Medicine, 29, 1511–1519.

NBER Digest. (2025, December). Consequences of organ procurement reform. National Bureau of Economic Research. https://www.nber.org/digest/202512

Obermeyer, Z., Powers, B., Vogeli, C., & Mullainathan, S. (2019). Dissecting racial bias in an algorithm used to manage the health of populations. Science, 366(6464), 447–453.

Ohno, T. (1988). Toyota production system: Beyond large-scale production. Productivity Press.

OPTN/SRTR. (2023). 2022 OPTN/SRTR annual data report. https://srtr.transplant.hrsa.gov

Organizacion Nacional de Trasplantes (ONT). (2025). Actividad de donacion y trasplante: Espana 2024. https://www.ont.es

organdonationreform.org. Oversight gaps and conflicts: The costly effects of an outdated organ donation system. https://costlyeffects.organdonationreform.org/Oversight/

Ozbay, E. Y., Tunc, S., & Ozaltin, O. Y. (2025). Incentives and performance in the U.S. organ donation system. NBER Working Paper. https://www.nber.org/digest/202512

Patzer, R. E. (2024). Bridging racial disparities in access to kidney transplantation. Journal of the American Society of Nephrology, 35(7), 959–961.

Patzer, R. E., Purnell, T. S., & Basu, M. (2023). Socioeconomic disparities in kidney transplantation. Clinical Journal of the American Society of Nephrology, 18(4), 554–564.

Prestalia, C. A., Gander, J. C., & Patzer, R. E. (2024). Care partner burden in the kidney transplant setting. Transplantation Reviews, 38(1), 100841.

Pyzdek, T., & Keller, P. (2018). The Six Sigma handbook (5th ed.). McGraw-Hill Education.

Reinhard, S. C., Feinberg, L. F., Choula, R., & Houser, A. (2023). Valuing the invaluable: 2023 update. AARP Public Policy Institute.

ResearchGate. (2025). Hypothermic oxygenated perfusion in extended criteria donor kidney transplantation: A randomized clinical trial. https://www.researchgate.net

ScienceDirect. (2024). Cold ischemia [overview]. https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/cold-ischemia

Scientific Reports. (2020). Decrease of renal resistance during hypothermic oxygenated machine perfusion is associated with early allograft function in extended criteria donation kidney transplantation. Scientific Reports. https://doi.org/10.1038/s41598-020-74839-7

Senate Finance Committee. (2023). Investigating UNOS: A review of the organization overseeing the nation's organ transplant system. U.S. Senate.

Sellers, M. T., et al. (2025). Normothermic regional perfusion performed by a U.S. organ procurement organization for non-thoracic organ donors. American Journal of Transplantation.

Springer Nature. (2025). Organ procurement organization-based normothermic regional perfusion in the US: Current state and future direction. Current Transplantation Reports. https://doi.org/10.1007/s40472-025-00471-x

Stewart, D. E., Levan, M. L., Gentry, S. E., Lonze, B. E., & Segev, D. L. (2026). Accumulated refusal count: A signal of kidney nonuse risk [Preprint]. medRxiv. https://doi.org/10.64898/2026.01.08.26343720

Tingle, S. J., Thompson, E. R., et al. (2024). Normothermic and hypothermic machine perfusion versus static cold storage for deceased donor kidney transplantation. Cochrane Database of Systematic Reviews, 2024(7), CD011671.

United Network for Organ Sharing (UNOS). (2026, January 28). U.S. surpasses 49,000 organ transplants while deceased organ donations dip. https://unos.org

United States Renal Data System (USRDS). (2023). USRDS 2023 annual data report. National Institutes of Health.

Wilson, J., & Nadler, J. (2025). Living Organ Donor Tax Credit Act, H.R. 3698, 119th Cong. https://www.congress.gov

Womack, J. P., & Jones, D. T. (1996). Lean thinking: Banish waste and create wealth in your corporation. Simon & Schuster.