ETCLC

ESRD Treatment Choices Learning Collaborative

The CMS/HRSA Kidney Donation & Transplant Initiative

ESRD Treatment Choices Learning Collaborative (ETCLC)

Kidney Donation Change Package

July 2025

Introduction

The 2025 Kidney Donation Change Package reflects the knowledge gained from the ETCLC and focuses on the effective practices employed by high-performing donor hospitals and organ procurement organizations (OPOs). It includes the use of a "driver diagram" format and eight "drivers" to simplify the presentation of strategies and concentrates on actionable change ideas that work to achieve the three ETCLC National Aims:

- Aim 1: Increase the number of deceased donor kidneys transplanted.
- Aim 2a: Decrease the current national nonuse rate for all procured kidneys with a kidney donor profile index (KDPI) < 60.
- Aim 2b: Decrease the current national nonuse rate of all procured kidneys with a KDPI ≥ 60.
- Aim 3: Increase the number of deceased donor kidneys recovered with a KDPI ≥ 60.

For the purposes of this change package, KDPI kidneys ≥ 60 have been categorized as "medically complex" kidneys. The term medically complex is intended to refer to those kidneys that can be recovered and transplanted into select individuals based on donor characteristics. Medically complex kidneys may not be suitable for all individuals but are appropriate for medically suitable recipients. These kidneys may require extra effort to identify a suitable recipient due to one or more factors (e.g., expected graft longevity, anatomy, infectious disease risk). The characteristics of a medically complex kidney stand in contrast with other kidneys (KDPI < 60) recovered for transplant. Kidneys with a KDPI < 60 should be transplantable into most individuals based on optimal donor characteristics that would benefit most patients.

The ETCLC's work suggests that the key to reducing the nonuse rate and increasing the number of deceased donor kidneys transplanted can best be achieved by increasing transplant program capacity and willingness to grow at rates higher than the current average rate (about 7% annually).

To ensure the appropriate supply level, donor hospital and OPO leadership, midlevel managers, and frontline staff are all encouraged to review this edition, assess the actions for adoption, and implement strategies to maximize the donation opportunity volume and preserve those organs for transplant.

Donation Change Package—June 2025

Driver	Action Item
1. Secure the Right Leadership	***The OPO and donor hospital executive leadership accept ownership of organ donation practices and commit to benchmark targets for growth and outcomes.*** i. Establish joint OPO and donor hospital collaboration to set bold goals guided by data and national priorities to increase deceased donor authorization, recovery, and allocation to improve kidney transplantation. ii. Create the expectation that donor hospital executives actively participate in donor-related committees and leadership efforts to drive organ donation performance. iii. Conduct regular OPO and donor hospital leadership meetings to review performance data and ensure continuous improvement. iv. Align OPO and donor hospital resources to ensure optimal donation and organ recovery system processes. v. Update hospital personnel, ensuring that leaders, physicians, and nurses understand their role in the donation process.
2. Establish a Culture of Accountability	***The OPO and donor hospital leadership define and establish a culture of accountability in which team members are held accountable for working together to achieve goals and resolve problems.*** i. Honor the first-person (donor) authorization. a. Maintain hospital support of the OPO in all cases where there is organ donor designation, ensuring the intention of the decedent to donate is honored and families are supported. b. Develop a donation policy between the hospital and OPO. Specifically, it should include a plan for escalation in addressing scenarios where the family is opposed to donation in the presence of a legal organ donor gift document. ii. Develop and maintain a shared philosophy of donation between the donor hospital and OPO with clearly defined goals. a. Establish a hospital-based organ donation council to include all relevant stakeholders (e.g., risk management, critical care, social work, donor families, and OPO). b. Include donation goals (e.g. zero missed opportunities) and metrics as part of hospital-wide performance improvement.

Driver	Action Item
	c. Share monthly metrics between the OPO and donor hospital and offer regular collaborative feedback to reach target goals. iii. Use feedback loops (e.g., provide ICU staff with outcomes from donors) to optimize the donation processes and outcomes for all stakeholders. iv. Ensure that any healthcare personnel declaring death are not at all involved in organ procurement to avoid conflicts of interest and preserve public trust.
3. Improve the Family Experience	***The OPO and donor hospital work together to enhance the donation experience for donors and families.*** i. Provide unconditional support from the hospital and OPO to families navigating the donation process. ii. Develop "cues" from the family for the hospital and OPO to coordinate and initiate the OPOs' timely approach for donation. Examples of cues include: a. The family holds no hope for survival. b. Brain death or grave prognosis has been declared. c. A decision was made to limit/withdraw life-sustaining therapy that would compromise donation opportunities. d. The family mentions donation. e. If donation is accidentally brought up by the care team (independent of the OPO). iii. Develop situation-specific communication strategies and talking points to ensure families receive compassionate and accurate information about organ donation. a. Train, educate, and deploy OPO staff as designated requestors for organ donation, providing families with clear and consistent messaging. b. Provide appropriate and timely communication to the patient's family that "all that could be done has been done" in the best interest of the patient. c. Assist the family in understanding the meaning of "brain death" or "circulatory death" and share medical results and brain imaging, as needed. d. Communicate expectations with the family around the time needed to recover organs and work with the family on how to say goodbye to their loved one. iv. Hold regular huddles between the OPO and hospital team to develop and implement a plan for how donation will be discussed.

Driver	Action Item
	v. Develop "culturally sensitive" communication strategies for communities that reflect the language and distribution systems that enable potential donors and donor families to make informed decisions about donation. vi. Introduce and engage palliative care teams to support families during decision-making. vii. Use donor recognition initiatives, such as Honor Walks and Donate Life flag ceremonies, to honor donors and their families and build community awareness about organ donation. viii. Conduct after action reviews (AARs), or debriefing sessions, ideally within 1 week of all potential organ donor cases, regardless of outcome to discover operational barriers to donation and improve future case strategies.
4. Manage the Donor	***The OPO and donor hospital manage the donor to preserve the opportunity to recover organs.*** i. Adopt broad clinical triggers for early identification of potential donors and promptly notify the OPO (e.g., ventilator patients and circulatory deaths), adjusting triggers when necessary. ii. Identify operational efficiencies to document medical records and minimize the length of time hospital staff are on the phone at the time of initial referral/call OPO notification. iii. Adopt OPO rapid (two-hour) and on-site (where practical) response protocols to referrals from donor hospitals for every potential donor scenario. iv. Establish clinical standards of practice and procedures for stabilization of potential donors, including the optimization of renal replacement therapy management through nephrology expertise and evidence-based clinical interventions. v. Use the standard definition of death to ensure that the determination of death is made in accordance with accepted medical standards. vi. Establish catastrophic brain injury guidelines at donor hospitals, which include standardized order sets that optimize the potential for organ viability. a. The OPO and donor hospital should work together to formalize these guidelines and provide ongoing staff education. b. Routine pre- and post-donor management debriefs between the donor hospital and OPO staff should be incorporated into donor management guidelines. c. Routine evaluation of the hospital donation after DCD policy should be reviewed with the OPO to confirm alignment with local and national standards. vi. Invite the OPO to attend patient rounds pre- and/or post-donor management strategies.

Driver	Action Item
5. Provide Continuing Education for Professionals	***The OPO and donor hospital collaborate to provide continuing education to staff involved in the donation process.*** i. Conduct comprehensive hospital-wide education, ensuring hospital staff know when to notify the OPO. Use clinical triggers to define standards of practice for "timely referral" of potential organ donors. a. Train clinical students on key donation topics, including brain death and circulatory death, to ensure accurate and compassionate communication with families. ii. Provide peer-to-peer educational opportunities (e.g., physician-to-physician training, critical care registered nursing [RN] mentorship programs). iii. Educate clinical staff about use of "transitional language" to introduce family care coordinators/OPO staff to the family.
6. Promote the Donation and Referral Process to the Community	***The OPO and donor hospital make donation a community priority.*** i. Strengthening community outreach and engagement through partnerships with high schools, faith-based organizations, departments of motor vehicles (DMVs), and first responders to promote donor designation. ii. Incorporate organ donation education into medical and nursing school curriculums. iii. Develop community awareness campaigns to highlight the urgency of kidney transplantation and the role of deceased donors in saving lives. iv. Use "Connect to Purpose" speakers, such as donor families and kidney transplant recipients, in departmental meetings and public events to build an understanding of kidney donation.
7. Use Data to Drive Improvements in Care	***The OPO and donor hospital use data to improve efficiency, effectiveness, quality of care, and the preservation of organs.*** i. Establish detailed performance tracking systems to monitor donation metrics, conversion rates, and kidney recovery outcomes. ii. Regularly review data and trends to adjust strategies and improve performance. iii. Benchmark donor hospital and OPO performance against regional and national performance. iv. Use electronic medical record (EMR) systems to streamline donor referrals and minimize delays in the donation process.

Driver	Action Item
8. Embrace Innovation	***The OPO and donor hospital systematically evaluate new concepts, methods, and technologies that are aligned with organizational missions and strategic objectives.*** i. Explore the use of innovative technologies to enhance donor identification and organ preservation, such as: a. Artificial intelligence and predictive analytics to streamline and optimize donor identification. b. Communication technology to provide remote donor assessments, stream real-time video of organ evaluation, and conduct rapid response meetings or pre-op huddles. ii. Establish donor criteria for the OPO to use normothermic regional perfusion (NRP) and communicate the use of NRP in kidney allocation. (See Appendix 1) iii. Establish the use of machine perfusion of kidneys at the OPO and donor hospital as a standard practice. (See Appendix 1) iv. Implement advanced donor management techniques to expand the criteria for acceptable kidney donations (e.g., acute kidney injury [AKI] kidneys, Hepatitis C-positive kidneys, human immunodeficiency virus positive [HIV+] kidneys). v. Pilot approaches to improve hospital-OPO collaboration and optimize the donation process. vi. Invest in research and best practices to continually advance the field of deceased donor kidney donation and transplantation. vii. Develop the OPO and donor hospital financial relationship to establish and support a Donor Care Unit to stabilize organ donors and optimize organ viability. (See Appendix 1) viii. Create an Organ Logistics/Transportation department within the OPO to reduce time between recovery, allocation, and organ transport/delivery. (See Appendix 1)

Appendix 1

The preceding effective practices were developed from interviews with high-performing donor hospitals and OPOs. During the ETCLC, many innovative practices were discovered and discussed within the collaborative. The following narrative highlights innovative practices that are emerging but are not necessarily considered effective practices because they have been identified without regard to meeting specific performance criteria. These innovative practices are presented to the reader for consideration to determine their applicability to his/her specific organization.

1. Implement Normothermic Regional Perfusion (NRP)

What It Does:
NRP restores oxygenated blood flow to abdominal organs after DCD, reducing ischemia-reperfusion injury and enhancing graft viability.

Benefits:

- Increases organ utilization, especially kidneys from DCD donors.
- Improves early graft function and transplant outcomes.
- Reduces delayed graft function (DGF).

Risks:

- Requires technical expertise in perfusion and surgical timing.
- Creates logistical challenges with equipment, staffing, and coordination.
- Poses ethical considerations regarding donor intervention timing.

Key Implementation Steps:

- Partner with skilled perfusionists or companies with cross-clamp experience.
- Engage an ethicist to help guide the organizations' use of NRP, including navigating potentially challenging conversations with the deceased's family members.
- Define clinical criteria for NRP use (e.g., warm ischemia time thresholds).
- Create protocols for transitioning from NRP to hypothermic machine perfusion (HMP).
- Establish allocation and transplant center communication procedures.
- Develop detailed transportation and cross-functional coordination plans.

2. Expand Use of Hypothermic Machine Perfusion (HMP)

What It Does:
HMP perfuses kidneys with a cold, oxygenated solution post-procurement to flush toxins, reduce ischemia, and enhance post-transplant performance.

Benefits:
- Reduces delayed graft function.
- Improves organ preservation for marginal donors.
- Potentially improves long-term graft outcomes.
- Enables continuous monitoring and circulation of fluids during transport.

Risks:
- Equipment costs and training needs.
- Potential for organ damage from incorrect machine settings.
- Availability limitations in rural or resource-limited facilities.
- Challenges in shipping including availability of commercial flights; use of couriers/drivers.

Key Implementation Steps:
- Set clear clinical indications for pump use (e.g., expanded criteria donors [ECD], DCD, marginal donors).
- Acquire and maintain appropriate perfusion equipment (pulsatile or continuous).
- Designate secure storage and use areas in hospitals and OPO offices.
- Train recovery and preservation teams in operation and troubleshooting.
- Establish transport policies (Nationwide Organ Recovery Transport Alliance [NORA] flights, cargo carriers, ground).

3. Establish Donor Care Units (DCUs)

What It Does:
DCUs provide centralized, specialized care for organ donors to improve donor stability and optimize organ recovery conditions, either within an existing hospital or at a free-standing, dedicated facility managed by the OPO.[1]

[1] Marklin GF, Brockmeier D, Spector K. The 20-year paradigm shift toward organ recovery centers: 2500 donors at Mid-America Transplant and broader adoption across the United States. *American Journal of Transplantation*.2023; 23(7): 891–903.

Benefits:

- Maximizes organ yield and viability.
- Reduces operating room (OR) scheduling delays and intensive care unit (ICU) transfers.
- Improves coordination of care and donor dignity.

Risks:

- Imposes an initial cost for infrastructure and staffing.
- Requires hospital or facility collaboration.
- Needs clear criteria to justify use over standard ICU care.

Key Implementation Steps:

- Define scope: donation after brain death [DBD], DCD, pediatric focus, or universal donor inclusion.
- Secure facility space (e.g., embedded hospital units, standalone OPO sites).
- Integrate protocols for donor management goals and real-time monitoring.
- Educate families and staff about the process and donor dignity.
- Pilot with selected donor types and scale based on impact.

4. Standardize Donor Management Goals (DMGs)

What It Does:

DMGs provide a structured approach to maintaining organ viability across multiple physiological domains.

Benefits:

- Increases transplantable organ count and quality.
- Reduces ischemic injury.
- Enhances consistency across donor management teams.

Risks:

- Creates a potential for over-standardization if not adjusted for donor variability.
- Requires continuous monitoring and team adherence.
- Poses possible increase in resource use in ICU settings.

Key Implementation Steps:

- Standardize the definition of death.[2]
- Establish clinical targets (mean arterial pressure [MAP], sodium levels, temperature, glucose, vasopressors).

[2] Lewis A, Kirschen MP, Greer D. The 2023 AAN/AAP/CNS/SCCM Pediatric and Adult Brain Death/Death by Neurologic Criteria Consensus Practice Guideline: A Comparison With the 2010 and 2011 Guidelines. *Neurology Clinical Practice*. 2023 Dec;13(6):e200189. doi: 10.1212/CPJ.0000000000200189. Epub 2023 Oct 11. PMID: 37829552; PMCID: PMC10567121

- Create protocols integrated into hospital electronic health record (EHR) or donor tracking systems.
- Train ICU and OPO staff to monitor and adjust parameters in real time.
- Audit compliance and outcomes for continuous improvement.

5. Build an OPO-Based Logistics Management Team

What It Does:
A dedicated logistics team streamlines the organ recovery and transportation process, ensuring optimal timing and communication.

Benefits:
- Reduces organ nonuse and ischemic time due to transport delays.
- Increases coordination with recovery and transplant teams.
- Provides real-time tracking and accountability.

Risks:
- Poses start-up costs (staff, training, dispatch software, equipment).
- Creates a need for 24/7 coverage and cross-training.
- Adds coordination complexity across hospital systems and vendors.

Key Implementation Steps:
- Hire and train logistics specialists (dispatchers, coordinators).
- Develop standards of procedure (SOPs) for all modes of transport (air, ground, courier).
- Implement Global Positioning System (GPS) tracking and notification systems.
- Establish metrics to monitor delivery times and cold ischemia duration.
- Partner with vendors and hospitals to align expectations and timelines.

This material was prepared by Health Services Advisory Group (HSAG), a Technical Assistance, Quality Improvement, and Learning Contractor under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services (HHS). Views expressed in this material do not necessarily reflect the official views or policy of CMS or HHS, and any reference to a specific product or entity herein does not constitute endorsement of that product or entity by CMS or HHS. FL-TAQIL-TQ4EFP-06172025-02