Documents for the Record

U.S. House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Hearing
["Ensuring Patient Safety: Oversight of the U.S. Organ Procurement and Transplant System"]
July 22, 2025

Majority:

1. March 24, 2025, Information Memo to the Associate Administrator submitted by Rep. Joyce
2. May 28, 2025, Kentucky Organ Donor Affiliates Corrective Action Plan and Organ Procurement and Transplantation Network Directive submitted by Rep. Joyce
3. April 13, 2021, UNOS News article submitted by Rep. Dunn
4. December 14, 2022, UNOS News article submitted by Rep. Dunn

Minority:

1. June 6, 2025, *New York Times* article submitted by Rep. DeGette
2. January 28, 2025, letter from Danella Gallegos submitted by Rep. Ocasio-Cortez
3. July 31, 2022, *Washington Post* article submitted by Rep. Trahan

HRSA
Health Resources & Services Administration
Health Systems Bureau/Division of Transplantation
5600 Fishers Lane
Rockville, MD 20857

DATE: **March 24, 2025**

TO: Suma Nair, PhD, MS, RD, Associate Administrator, HSB

FROM: Division of Transplantation

SUBJECT: INFORMATION ONLY – HRSA-directed investigation into KYDA

KEY INFORMATION

HRSA has become aware that clinical practices at Kentucky Organ Donor Affiliates (KYDA), the organ procurement organization (OPO) responsible for Kentucky and parts of Ohio and West Virginia, may create potentially avoidable risk of bodily harm and death to neurologically injured patients. The Organ Procurement and Transplantation Network (OPTN) has been investigating a related matter through the OPTN's safety and review processes, and, to date, these practices appear to be ongoing. The Health Resources and Services Administration (HRSA) Division of Transplantation (DOT) regulatory and oversight authorities under the National Organ Transplant Act (NOTA)[1] and HRSA's implementing regulations at 42 CFR part 121, as delegated by the Secretary, permit HRSA to take additional actions to protect the health and safety of local donor patients and families as well as the integrity of the national procurement and transplant system. **Records provided to HRSA show potentially serious and ongoing risk to patients and families, as well as failures by KYDA and the OPTN to adequately recognize and respond to poor patient care and quality practices.**

EXECUTIVE SUMMARY

On September 11, 2024, the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations held a hearing to "[e]xamine efforts to strengthen oversight, improve accountability, and address conflicts of interest within the OPTN," and to "inquire about ongoing patient safety concerns" in the setting of one year having passed since the passage of the Securing the U.S. Organ Procurement and Transplantation Network Act.[2,3] The Committee shared a letter written in regard to KYDA[4]. In this letter, a former KYDA employee alleged that

[1] See: 42 U.S. Code § 274 et. seq
[2] "A Year Removed: Oversight of Securing the U.S. Organ Procurement and Transplantation Network Act Implementation." House Energy and Commerce Committee Subcommittee on Oversight and Investigations hearing announcement, 9/4/2024. https://energycommerce house.gov/events/oversight-and-investigations-subcommittee-hearing-a-year-removed-oversight-of-securing-the-u-s-organ-procurement-and-transplantation-network-act-implementation
[3] Securing the U.S. Organ Procurement and Transplantation Network Act of 2023, Pub. L 118-14 (amending 42 USC § 274).
[4] On October 1, 2024, Kentucky Organ Donor Affiliates merged with a neighboring OPO in Ohio and became Network for Hope. For consistency, the OPTN code KYDA will be used in this document.

in 2021, a patient had been inaccurately pronounced brain dead and was pursued as an organ donor by KYDA. Per this report, the patient, who was the victim of a drug overdose, showed clear signs of life at multiple points, but KYDA senior staff directed that organ recovery proceed. The incident reporter further claimed that only after action by the procuring surgeon, who refused to participate in the recovery, was the operation halted and the patient transferred back to the ICU. Finally, the incident reporter claimed that the patient had been discharged alive from the hospital. The story gathered immediate and widespread media attention.[5,6] Two days after the hearing, the incident reporter was fired from her role at another business in the procurement industry following a complaint to that company by KYDA.[7]

On September 12, 2024, the OPTN contractor, United Network for Organ Sharing (UNOS) sent a letter to KYDA requesting a narrative description of case KYDA-001,[8] as well as documents including information on donor referral, brain death testing, perioperative and hemodynamic data, communications with hospital staff and transplant centers regarding the case, evidence of reporting of root cause analyses, corrective actions, and reporting of an adverse event. In response, KYDA provided a single page letter stating that KYDA-001 was not a brain death case and the incident reporter had no personal involvement in the case. KYDA provided none of the information requested by the OPTN, and summarized the case as follows:

> *"The potential donor was treated following standard protocols for DCD [donation after circulatory death]. The proper guardrails were in place and worked to the expectations, policies, and procedures of all regulatory agencies . . . KYDA is satisfied and confident in the donation process for [KYDA-001]."*[9]

OPTN Membership and Professional Standards Committee (MPSC) leadership discussed KYDA's response in a regularly scheduled meeting on September 24. At that time, the MPSC concluded that the allegations were unfounded and closed the case. HRSA deliberated internally, and based on KYDA's failure to return any of the requested documents, determined that the KYDA response was insufficient. On October 1, HRSA directed the OPTN to reopen the investigation.

On October 7, 2024, KYDA returned partially redacted copies of documents that had been requested by the OPTN on September 12. In these documents, contemporaneous notes by KYDA staff in their internal electronic medical record (EMR) showed a narrative of events that may

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[5] "Medical Group Accused of Seeking to Collect Organs From Patient Who Was Still Alive." Wall Street Journal, 9/11/2024. https://www.wsj.com/us-news/organ-supply-group-accused-of-seeking-to-collect-organs-from-patient-who-was-still-alive-bc4f9bb9

[6] "Kentucky organ recovery group accused of pursing transplant before patient died." Richmond Times-Dispatch, 9/12/2024. https://richmond.com/news/local/business/health-care/kentucky-organ-recovery-group-accused-of-pursuing-transplant-before-patient-died/article_0e5b48ee-7062-11ef-9384-43d79b59013d html

[7] "Whistleblower Fired After Making Organ-Collection Allegations." Wall Street Journal, 9/24/2024. https://www.wsj.com/us-news/whistleblower-fired-after-making-organ-collection-allegations-b56c1d99

[8] Though the patient's name has been shared in subsequent media reporting, for the purposes of this memo, we will refer to the index case as "KYDA-001." Records reviewed as part of subsequent requests of the OPO will be similarly deidentified with a 'KYDA-' prefix and a unique nonsequential three digit suffix.

[9] Julie Bergin, CEO of KYDA, to OPTN 9/20/2024.

have posed preventable harm to patient KYDA-001. At multiple points, KYDA staff recognized the patient as having a high and increasing level of neurologic function, but did not deviate from plans for DCD organ recovery. In OPO nomenclature, the process by which a patient's status is reassessed is referred to as "assessment of goals of care" and is a standard of practice. As this clinical course unfolded, KYDA staff also documented instances of hospital staff speaking up with concerns:

> *"Hopsital [sic] staff was extremely uncomfortable with the amount of reflexes patient is exhibiting . . . Hospital staff kept stating that this was euthanasia and [KYDA staff member] explained to them that it is not."*[10]

KYDA's cover letter for these documents closed with the same statement as their initial letter: "KYDA is satisfied and confident in the donation process for [KYDA-001]." Based on this response, on October 18, 2024, HRSA directed the OPTN and KYDA to provide materials from similar cases undertaken by KYDA after the date of the index case.

As the investigation into the index case unfolded, on October 3, 2024, the Association of Organ Procurement Organizations (AOPO), an industry trade group representing the majority of OPOs, released a press release to publicize an open letter referencing UNOS's own description of the September 11, 2024 Congressional hearing as "unfounded accusations."[11] The letter characterized the ongoing effort to improve patient safety through enhanced oversight as a "misinformation conspiracy campaign," and concluded "[i]t is time for it to stop." Among the signatories to this letter were more than 20 UNOS staff signing with their corporate affiliation, including the Chief Executive Officer, Chief Legal Officer and General Counsel, Special Counsel for Contract Operations, and the Director of Member Quality and Contract Operations. Additional signers included two current members of OPTN Board of Directors and a member of the MPSC. In the opinion of HRSA, these signatures created potential for conflicts of interest. HRSA has proceeded with parallel investigative processes. The OPTN and UNOS were directed to proceed with reviewing materials received responsive to HRSA's October 18 direction, and, on November 20, 2024, HRSA requested clarification from contractor staff on a plan to mitigate the potential conflicts of interest as identified given the above-referenced AOPO letter. HRSA supplemented its direction on December 6, 2024 with an additional requirement for the OPTN's investigation into KYDA to exclude any individual who had signed the AOPO letter. Finally, in response to further anonymous reporting of a concerning case from December 2024, on January 8, 2025 HRSA directed that KYDA supply, and the OPTN review, patient records from attempted DCD procurements through the end of calendar year 2024.

The OPTN presented the findings of its investigation at meetings of the OPTN Board of Directors on February 27 and March 3, 2025. The OPTN's final four page report stated "*overall, there were no major concerns or patterns identified. While no major issues were found,*

[10] KYDA-001 OPO chart; received as attachment to letter from Julie Bergin, 10/7/2024.
[11] AOPO press release, 10/3/2024 [letter linked on page]. https://aopo.org/transplant-advocates-campaign-of-misinformation-causing-drop-in-registered-organ-donors-and-threatening-lives-of-patients/

reviewers pointed out a few small areas of improvement."[12] The OPTN president, in leading the discussion on February 27, characterized patient KYDA-001's case as "*unusual as the patient recovered significantly more than would have been expected under ordinary circumstances, which is kind of a nice story for the family, honestly*." Following discussion of potential options, the Board voted on the following recommendation to the Secretary regarding KYDA (full report in Appendix I):

> "*The OPTN recommends the Secretary (1) require KYDA to perform a root cause analysis of KYDA's failure to adhere to its own policies, including, but not limited to, failure to comply with the Five Minute Observation Rule, (2) require KYDA to develop and adhere to a KYDA policy that clarifies who is a suitable candidate as a DCD donor, and (3) require KYDA to develop a policy that allows any individual to stop progression of a donation if they identify a patient safety issue*."

In addition to the OPTN investigation, HRSA staff have reviewed source material from the index case and cases identified through HRSA's related directions to the OPTN. Additional clinical records relating to KYDA-001's case were also provided by the patient's next of kin during this period and have been reviewed.

Specifics of both the index case and subsequently identified similar donor patient cases are discussed below. Though case details vary, patterns on the part of KYDA were identified:

1. Failure to recognize neurologic function inconsistent or unfavorable for DCD organ recovery on initial patient assessment or subsequent follow up.
2. Failure to work collaboratively with patients' primary medical teams, including instances of potential violation of separation of roles in patient care.
3. Failure to respect family wishes and appropriately safeguard the decisionmaking authority of legal next of kin.
4. Failure to follow professional best practices as well as policies and guidelines for collection of patients' medical data.

The prevalence of these patient-level failures in KYDA's practices suggests organizational dysfunction and poor quality and safety assurance culture at KYDA. Cases strongly similar to the 2021 index case were found to have occurred as recently as December 2024. **Cumulatively, evidence available to HRSA suggests there may be ongoing risk of harm to patients in KYDA's donation service area (DSA). Anecdotal evidence in contemporary popular media reporting suggests broader harm to the transplant system, as public faith in organ procurement suffers and individuals remove themselves from donor registries.**[13]

Decisive action to address unsafe care by KYDA and provide objective and transparent oversight of all OPOs is central to the aims of the OPTN Modernization Initiative, as it will measurably

[12] "Findings of the HRSA-Directed Investigation of Network for Hope," report to OPTN Board of Directors, 3/4/2025.
[13] "People opt out of organ donation programs after reports of a man mistakenly declared dead." Associated Press, 10/28/2024. https://apnews.com/article/organ-donor-transplant-kentucky-8f42ad402445a91e981327abb009906c

improve accountability, fairness, and performance within the United States' procurement and transplant system.[14] Prompt and definitive measures in this matter are also consistent with the National Academies of Science, Engineering, and Medicine (NASEM) recommendation that "*HHS should take actions to reduce variations in the performance of donor hospitals, OPOs, and transplant centers and increase the reliability, predictability, and trustworthiness of the U.S. organ transplantation system.*"[15]

INDEX CASE (KYDA-001)

Patient KYDA-001 is a young man with a medical history notable for illicit drug use who presented to a hospital in northern Kentucky with cardiovascular collapse after an unintentional overdose of methamphetamine in the early morning of 10/25/2021.[16] He was unresponsive and intubated at the time of arrival at the hospital. KYDA was contacted within 8 hours of the patient's arrival on 10/25, and came onsite that day. KYDA's first note documents the patient's Glascow Coma Scale (GCS) as 3T, with no pupillary, corneal, or pain responses and no overbreathing the ventilator.[17] At the time of this assessment, the patient was receiving three different sedative agents in the aftermath of his initial presentation.

KYDA followed the patient for the next two days, documenting depressed mental status with GCS of 3T and minimal reflexes as sedation was weaned. The primary medical team's note on 10/27 documented the plan: "*discussion had with patient's family today. They would like to proceed with terminal wean. We will wait until they can arrange for a time to be present.*" The family was approached by KYDA with documentation that KYDA-001 had signed the donor registry, and the legal next of kin gave consent to proceed with DCD procurement. At this point, the case was following a standard DCD clinical course, where the family and hospital make the determination to remove life support, and then the OPO approaches with the possibility of organ procurement. From that point until the patient expires, the hospital and primary medical team

[14] HRSA OPTN Modernization Initiative announcement, 3/22/2023.
[15] NASEM: Realizing the Promise of Equity in the Organ Transplantation System, 2022.
[16] Clinical events throughout case discussion based on documentaion in KYDA and hospital files.
[17] Note on bedside neurologic tests: GCS is used to assess level of neurologic injury based on eye opening, motor function (movement), and speech. The scale ranges from 3 to 15. A completely awake and intact patient has a GCS of 15. A dead patient, either from cardiac or brain death, would have a GCS of 3, as would a patient sedated to the point of complete anesthesia (as for surgery). Sedation and paralysis complicate clinical assessment of brain function. The highest GCS that any intubated patient, such as a neurologically intact person emerging from surgical anesthesia, can have is 10T. Brain stem reflexes also serve as bedside assessment tools, checking whether there are physiologic responses to bright light in the eyes (pupillary), touch on the surface of the eye (corneal), and painful stimuli such as sternal rubs or pinches. Additional reflexes include coughing and gagging with manipulation of the breathing tube or suctioning of the lungs. "Breathing over the ventilator" refers to patients having preserved respiratory drive (initiating their own breaths). Lower GCS and fewer reflexes indicates more profound injury, deeper sedation, or a combination of the two. A brain dead patient would persist in a GCS of 3T with no reflexes off sedation.

must remain involved, as the patient is still alive and under their care.[18,19] In most situations, this is a collaborative process, in which the OPO makes recommendations for hemodynamic support and requests that tests such as bronchoscopy and cardiac catheterization be performed, and the hospital then executes these as patient care orders until extubation is performed.

In KYDA-001's case, however, the OPO and hospital followed this plan to the letter while failing to reassess the decision to pursue organ recovery. On the morning of 10/28, the hospital note says "*KODA is present and taking over*." In the next two days, multiple hospital notes reference 'KODA directions' and 'KODA requests.' The OPO record reflects the separation of roles, including "*huddled with the cath lab team prior to starting and explained to them that the patient was still under the hospitals care and not KODA. That all interventions would come from providers*."

In the same time frame, hospital and OPO staff were documenting improving neurologic function. The OPO clinical notes do not contain any further GCS assessments after authorization for procurement was obtained, but the note on 10/28 includes "*strong cough and gag*." On the morning of 10/29, the patient was taken for a diagnostic cardiac catheterization. Hospital staff noted how active and aware the patient was, as recorded in the OPO record:

> *"While patient was on the table patient purposeful movement to pain trying to grab while MD was gaining access. Patient eyes open and tracking. Thrashing on the bed."*
>
> *"[Cardiologist] made comment 'I am no neurologist but if [sic] I would most certainly call this purposeful movement and they should not have said that patient was not going to have a meaningful recovery with these reflexes.'"*

The note also records that the patient was sedated and paralyzed to allow the procedure to continue. The KYDA coordinator recorded the hospital staff's concerns:

> *"Hopsital [sic] staff was extremely uncomfortable with the amount of reflexes patient is exhibiting . . . Hospital staff kept stating that this was euthanasia and [KYDA staff member] explained to them that it is not."*

The coordinator ends this note with a statement that she will continue to provide education to the staff throughout the day, and that she has updated her superiors. There is no documentation of discussions among OPO staff to reconsider suitability for DCD in light of hospital concerns.

At 1:43 pm the same OPO coordinator noted continued neurologic improvement: "*Patients reflexes have seem [sic] to be improving. Patient is awake in the room. Will wiggle his toes in the right lower extremity to command*." She noted that he was overbreathing the vent and has intact pupillary, gag, cough, gag, and pain responses. She ended the note with "*reviewed with [administrator on call]*." Thirteen minutes later, there is a new note: "*After reviewing with*

[18] See: C.F.R. § 486.322 and § 485.643
[19] See: OPTN Policy 2.15.B

[administrator on call] - we will ask nursing staff to hold on sedation to properly assess neuro status." There are no further neurologic assessments documented by the OPO prior to going to the OR.

Between 5 and 6 pm, the patient was brought to the operating room, with family accompanying them down the hallway in a ceremony known as an honor walk. The patient was brought into the operating room, but there are no notes documenting whether they were moved to the OR table. Contemporaneous documentation from both hospital and OPO staff reflect the patient's high neuro status, as well as evidence of discomfort and fear as this process was carried out:

> *"As we were leaving for the honor walk, the patient started to wake up and exhibit reflexes he had all day. His eyes were open all the way down to the OR."* [OPO EMR]
>
> *"When entering the OR room and moving patient on the table the patient became extremely agitated and pulling his knees to his chest and waking up more. As the OR staff was prepping him and [hospital physician] was at the head of the bed the patient was shaking his head no and tears were rolling down his face."* [OPO EMR]
>
> *"While in OR and during during the process of preparing the patient for extubation, patient became agitated, restless and clearly uncomfortable; he periodically appeared aware of his surroundings. 2 doses of morphine sulfate 3 mg each were administered with partial improvement. Due to technical difficulties, we were not able to administer Ativan, Haldol or ropinirole."* [hospital EMR]

The patient spent approximately 45 minutes in the operating room before the palliatitive care physician ended the attempted recovery:[20]

> *"It was obvious that the staff was extremely uncomfortable. [KYDA staff] stepped out of the OR and [hospital physician] followed and stated that she felt that this was inhumane and unethical and she would not participate in this process.* [OPO EMR]
>
> *"[KYDA staff] immediately called [administrator on call] and asked for guidance. Prior to receiving call back [physician] had already made her decision and went and spoke with family that we would not be proceeding."* [OPO EMR]

The hospital physician's discomfort with the process may have been in part due to the fact that she had only met the patient once, approximately an hour prior to the beginning of the recovery attempt. Patient KYDA-001 had received a large dose of morphine prior to her assessment, and less than an hour before recovery showed little sign of his true neurologic condition:

> *"She did express concerns in [waiting area outside OR] as she did not think the patient would pass but it was 5 minutes prior to going to OR and for future reference what we*

[20] Though including documentation for perioperative billing purposes, the hospital record as provided to HRSA is missing the circulating nurse's note which would include times in and out of the room and staff present for the case.

could [sic] do to prolong the process [ie, give more time to evaluate the patient] . . . Patient had just received bath and 4 mg of morphine prior to her arrival so patient was restign [sic] comfortably when she did her initial assessment." [OPO EMR]

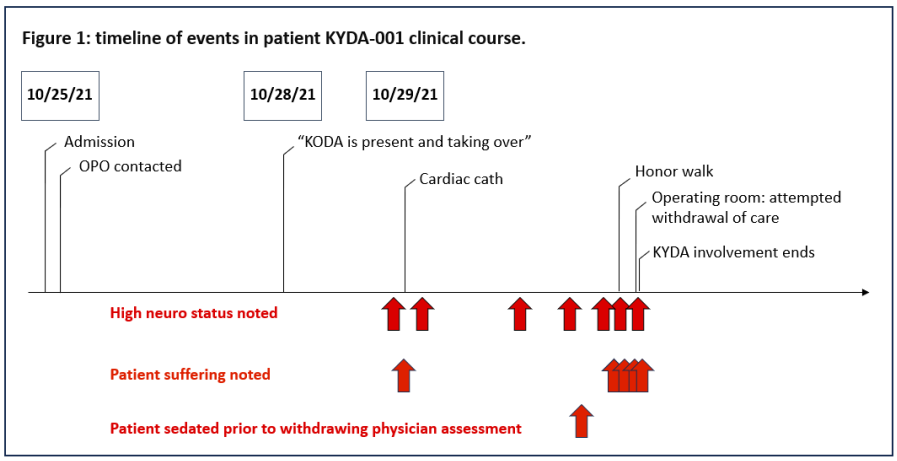
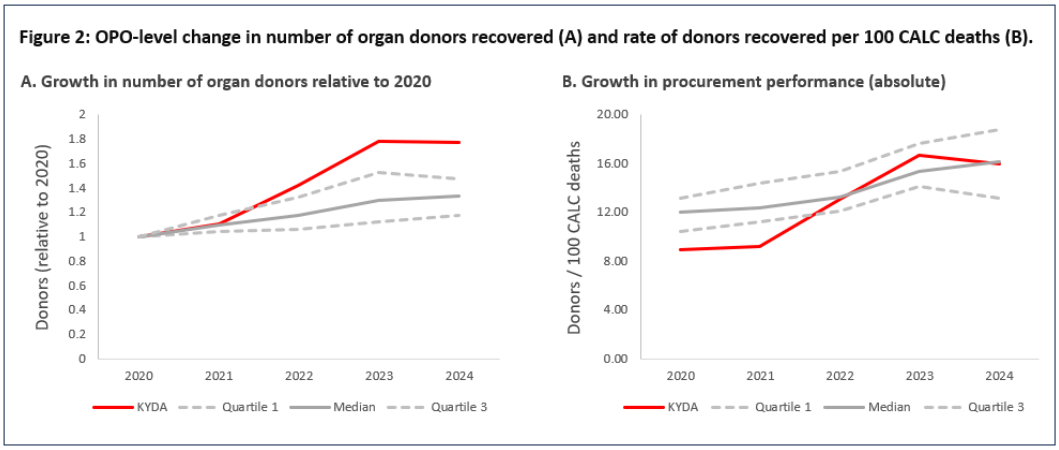


Figure 1 displays a simplified timeline of events in patient KYDA-001's care. KYDA staff documented improving neurologic status and concerns from physicians and nurses, but there is no evidence of deliberative process to reassess the likelihood that this would be a successful organ recovery. Instead, there was a worsening pattern of harm to the patient, with suffering documented during the cardiac cath and perioperative events. Fractured communication also seems to have created a sense of urgency and predetermined outcome that contributed to a misunderstanding of the patient's true neurologic status by the withdrawing physician.

While KYDA-001 did survive the events surrounding the attempted withdrawal of life support and organ procurement, the repeated assessment by KYDA that it is "*satisfied and confident in the donation process*" is incongruous with the facts of the medical record. An OPO coordinator followed the patient for 12 hours, documenting improving neurologic status and statements of concern from licensed nurses and physicians, escalating these to her leadership. The OPO expressed a plan to hold sedation and reassess candidacy, but instead the only documented assessment is from a hospital physician after the patient had received opioid sedation immediately prior to going to the OR. The OPO documented concerns among staff in the cath lab, ICU and OR, but there is no record of additional support or education occurring as a response to this case. While the features of the case show a single poor outcome, the assessment of it as "*a standard DCD OR [operating room]*" suggest deeper problems with KYDA's processes.[9,10]

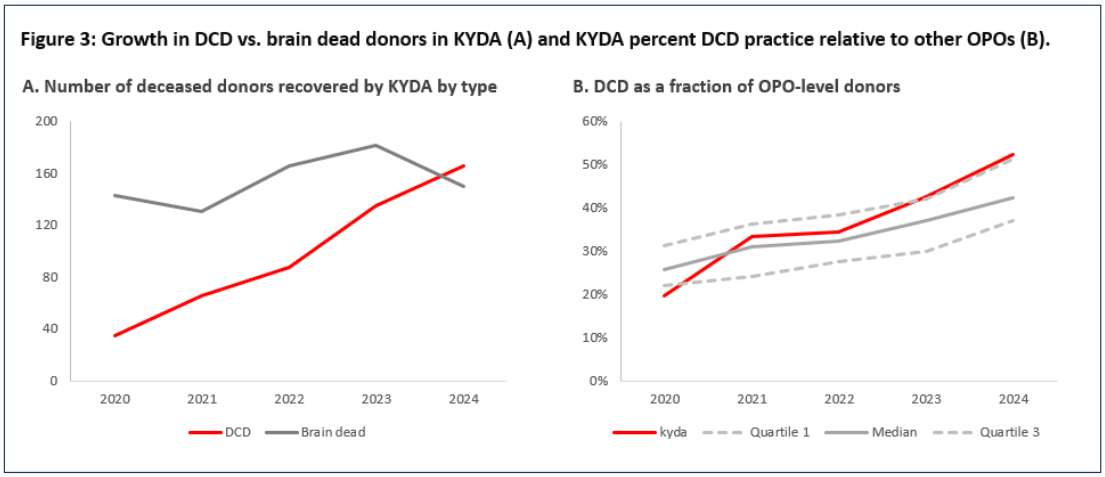
BACKGROUND ON ORGAN PROCUREMENT BY KYDA

Despite recent increased in donor recoveries, KYDA continues to be a low-performing OPO. As shown in **Figure 2A**, the number of organ donors recovered by KYDA has grown by 80% in the past five years, compared to 58% overall growth in the United States.[21] In part, this is attributable to the opioid epidemic, with overdose death rates in Kentucky, West Virginia, and Ohio all consistently ranking among the highest nationwide.[22] In addition to increases due to epidemiologic factors, KYDA has had improvement in procurement performance as measured using the CMS metric of donors per 100 cause, age, and location-consistent (CALC) deaths (**Figure 2B**).[23] In the most recent CMS assessment, based on 2021 data, KYDA remains in the poorest performing tier (Tier 3) of OPOs, though the shortfall to achieve a Tier 2 ranking has dropped from 37 donors in 2019 to only 17 donors in this observation period.[24]

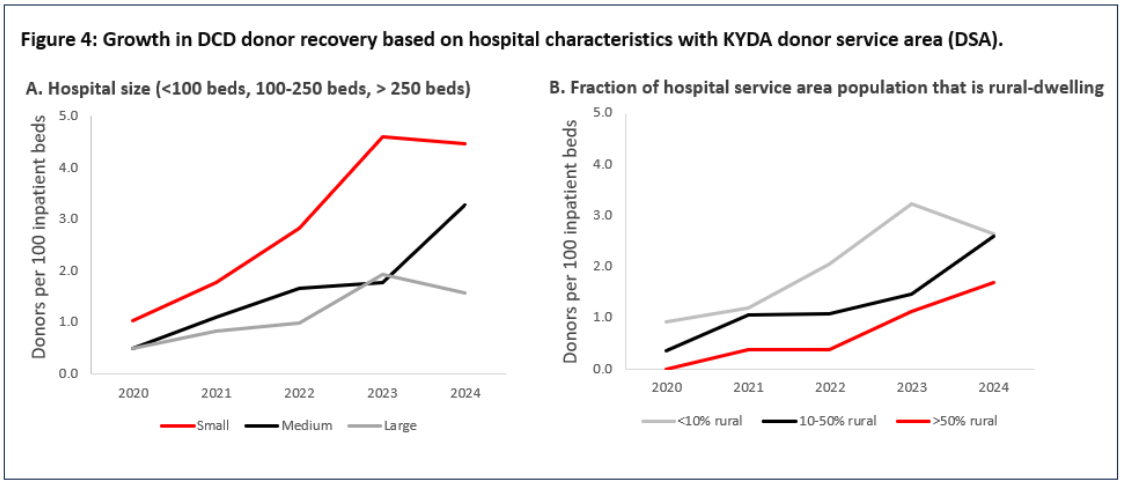


The gain in organ donors recovered by KYDA came almost entirely from increases in DCD. As shown in **Figure 3A**, the number of brain dead donors recovered by KYDA has been stagnant since 2020, while DCD donors rose from 35 in that year to 163 in 2024. As shown in **Figure 3B**, KYDA's shift to majority-DCD practice now places it at the 82nd percentile among OPOs in terms of DCD vs. brain dead procurement.[21]

[21] Data from: OPTN data 1/1/2020 – 12/31/2024.
[22] Drug overdose mortality by state, 2020-2022. National Center for Health Statistics. https://www.cdc.gov/nchs/pressroom/sosmap/drug_poisoning_mortality/drug_poisoning.htm
[23] Data from: OPTN data 1/1/2020 – 12/31/, National Center for Health Statistics Multiple Cause of Death (NCHS MCOD) data 1/1/2020 – 12/31/2023, forecast for 2024.
[24] CMS Organ Procurement Organizations Annual Public Aggregated Performance Report 2023. https://www.cms.gov/files/document/opo-annual-public-performance-report-2023.pdf



While DCD increased throughout KYDA's DSA, there were disproportionate gains in procurement in certain sectors.[25] As shown in **Figure 4A**, the increase in DCD procurement by KYDA was greatest in hospitals with less than 100 beds.[26] Hospitals serving majority rural patient populations had numerically lower organ procurement rates than those with more urban service areas, but even these hospitals demonstrated substantial gains from historically near-zero donor activity prior to 2021, as seen in **Figure 4B**.[27,28]



[25] Doby BL, Casey K, Ross-Driscoll K, et al. (2023) Am J Transplant 23(11):1793-1799.
[26] Homeland Infrastructure Foundationa Level Database (HIFLD). https://gii.dhs.gov/HIFLD
[27] "How we define rural." HRSA.gov https://www.hrsa.gov/rural-health/about-us/what-is-rural
[28] Dartmouth Health Atlas Supplemental Data: geographic boundary files. https://data.dartmouthatlas.org/supplemental/#boundaries

REVIEW OF CASES SUBMITTED FROM KYDA

Review of additional cases submitted by KYDA was informed by preliminary findings from the index case. Elements of interest included the overall medical presentation and initial and subsequent neurologic status of patients, staff interactions with patient families and primary medical teams, and evidence of robust documentation and quality assurance procedures.

Of note, the cases requested by HRSA and provided by KYDA are those in which patients were considered for DCD recovery but no organs were transplanted, as this was the outcome for patient KYDA-001. These cases are known as "authorized, not recovered" (ANR) patients. By definition, ANR cases do not include those patients from whom organs were recovered, and so HRSA's analysis cannot assess the quality of care for patients from whom organs were recovered. In consequence, this analysis is unable to assess the frequency of certain adverse events or problematic OPO practices, especially those that might increase the likelihood that a neurologically injured patient would die within a given timeframe (ie, hastening death).

High-level assessment of features of submitted cases

Among 360 cases submitted, there were 351 unique ANR patients on whom sufficient documentation was provided to assess elements of clinical presentation and care. The completeness and quality of records for cases varied, with variable inclusion of supporting documentation. Case lengths and reasons for non-recovery varied considerably, with some patients expiring during the evaluation process, others being aborted due to medical rule outs or lack of interest in patient organs, and many for whom the withdrawal of treatment (WOT) in a controlled setting did not progress to death. A total of 103 cases (29.3%) had concerning features, including 73 patients (20.8%) on whom either the initial or subsequent neurologic findings should have prompted earlier consideration of terminating DCD recovery. At least 28 (8.0%) patients had no cardiac time of death (CTOD) noted, with discharge to hospice, rehabilitation facility or home noted in some cases.[29]

Figure 5 displays the relative frequency of ANR cases compared to successful DCD recoveries at hospitals throughout KYDA DSA. As shown, there were proportionately more ANR cases per successful donor procurement at smaller hospitals and those with higher proportions of rural patients. As shown in **Figure 6**, a higher fraction of the ANR cases at small hospitals and those with more rural populations showed features of concern. **Cumulatively, these trends suggest that patients may experience variable care from KYDA depending on the hospital in which they are seen.**

[29] This does not include patients from November-December 2024, whose index admission may still have been ongoing at the time of data submission.

Figure 5: Authorized, not recovered (ANR) cases per DCD donor, by hospital characteristic within KYDA DSA 2021-2024

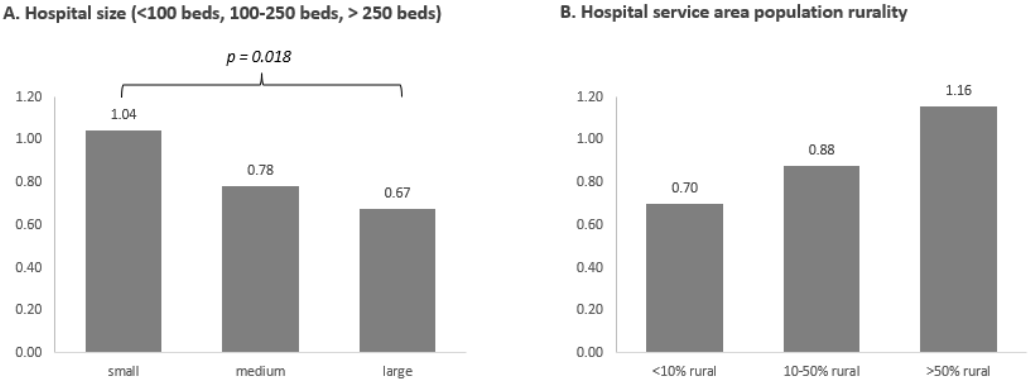
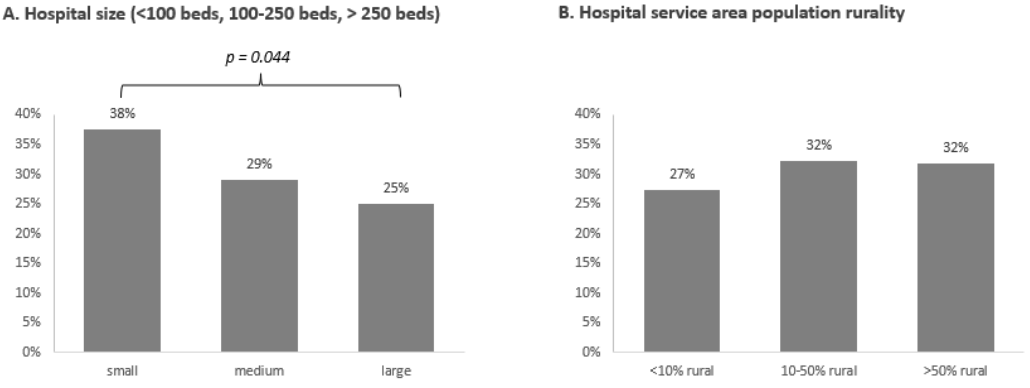


Figure 6: Fraction of ANR cases with concerning features by hospital characteristic with KYDA DSA, 2021-2024



In review of ANR cases, several themes of clinical and procedural concerns were identified. Representative examples are given below.

Issues with patient family interactions

> "*[Next of kin] verbalized that this would be too much for her mother and she did not want to put her through this. I explained by [patient] making the selfless decision to save lives that we would have to honor her decision and the document of gift is a legal binding document. I explained that I would talk to the team, and shared with LNOK that I wanted to be transparent and most likely we would not be able to accomodate her request . . .*" [case KYDA-031, 2023]

In the case referenced above, the patient had signed the donor registry maintained through the Kentucky Transportation Cabinet. Self-designation as a donor is also described as first person authorization (FPA). The OPO staff were requesting that the patient's next of kin complete a

separate authorization, as the Kentucky Revised Statute (KRS) governing anatomical gifts[30] specifies that prior authorization made by an individual only goes into effect only after death.[31] Therefore, the Kentucky OPO must obtain additional, specific consent from the legal next of kin in order to pursue donation after cardiac death, as the patient is pre-mortem and any first-person authorization is not in effect under Kentucky statute. This authorization is used by the OPO to undertake laboratory testing and imaging procedures on the still-living patient which are critical to evaluating organ function. In some instances, the OPO staff document that they followed the "FPA opposition process map," a document not provided to HRSA.

In case KYDA-191, an adult male who had not been on the donor registry suffered a neurologic injury in 2023. KYDA approached his brother, who had cognitive impairment and was noted as "*child like*" at the time of the authorization discussion. The patient had a GCS of 6 and intact reflexes, and was breathing spontaneously with minimal support. After a hospital physician and the unit manager verbalized concerns that the next of kin did not understand the DCD process, a repeat discussion was held the following day and the decision to proceed was reversed.

In case KYDA-263, also in 2023, OPO staff proceeded with obtaining authorization from two family members despite witnessing the next of kin take psychoactive medication immediately prior to the consent discussion. OPO staff documented impairment on the part of both family members during the consent discussion, as well as concerns from multiple hospital staff that the family were "*clearly inebriated*" and "*high off of something*."

Issues with medical assessments and healthcare teams interactions

As noted above, a central tenet of DCD procurement is that until the patient has passed, they remain under the care of the hospital's medical team.[18,19] In practice, once authorization to proceed has been granted by the family, the OPO and hospital teams collaborate, with OPO staff using licensed practioners to enter orders for diagnostic tests and patient management orders. In multiple instance in the submitted records, this procedure was violated:

> "*MD was concerned bc KODA coordinator was asking for tests to be ordered before KODA had consent. There were concerns about who will pay for those tests since MD didn't feel they were needed for his plan of care for the patient and the family had not been approached . . . He has no problem ordering test per KODA request after family consents to donation, but has ethical concerns with this occurring prior to consent. He stated this is also happening when we are doing routine follow-ups and confirmed we are asking for more than just "routine labs." I again stated I will follow-up on this issues as this isn't our practice and shouldn't be happening*." [case KYDA-049, 2022]

Poor communication and non-collaborative interactions with intensive care unit nurses and physicians are documented in multiple instances. In case KYDA-361, the following was written by OPO staff (underlining added for emphasis):

[30] See: KRS 311.1911 - 1955
[31] See: KRS 311.1911(3) ""Anatomical gift" means a donation of all or part of a human body to take effect **after the donor's death** for the purpose of transplantation, therapy, research, or education"

> "*[Physician] entered a note "Will await further direction in terms of timing for complete comfort measures from family/KODA. There is no documentation in the chart from KODA, I have had no direct communication from them, they placing [sic] demands for orders that have been placed under my name. Also note that patient has a very strong cough, was able to lift head off bed yesterday and is currently tolerating PS of 12 very well [minimal breathing support]". . . it seems as if the hospital care team is bothered by their own personal opinion on if this pt will pass within the 90min time frame; but it has been discussed that we will do what we need to do to honor the pt and families wishes of being an organ donor and give them this oppportunity; family is well aware of a clinical picture that it can not be predicted on if the pt passes in 90mins or not and they still want to proceed with the donation opportunity*."

In this case, which occurred after KYDA was aware of the HRSA-directed investigation in 2024, the patient survived for 14 hours after extubation, and the family was described as "*not doing well*" after he eventually passed.

Multiple submitted cases contain cause for concern regarding KYDA staff's assessment of patients' stability and suitability as donors. In a case from 2024, an OPO coordinator recorded these responses from aggressive kidney centers for a hepatitis C positive patient in refractory shock with widespread septic emboli:

> *[Center 1] " absolutely not" I don't even need to call my surgeon*
> *[Center 2] Not interest- why would we even approach on this*
> *[Center 3] Not interest didn't even got past septic emboli*
> *[Center 4] No interest*
> *[Center 5] interest Not transplantable*
> *[Center 6] No patients on list*
> *[Center 7] absolutely not*
> *[Center 8] stopped me at infarct*

The patient had recovered from a poor initial neurologic exam to a GCS of at least 7, intact reflexes and spontaneous respirations before the case was shut down due to lack of interest from transplant centers in organ offers [KYDA-027].

The cumulative effect of fractured communications and inflexible decision-making is apparent through multiple provider complaints and incident reports to the OPO. Among these were that nurses were refusing to take a potential-donor patient in the ICU over concerns about KYDA's management, that the placement of a central line in another patient for KYDA led to a serious complication requiring further invasive procedures, and that hospital staff felt that they had been "burned" by the OPO in clinical interactions.[32] Providers relayed their concerns for the effect of these practices on families:

[32] Cases KYDA-371, KYDA-167, and KYDA-342, respectively.

"[Hospital provider] is posing this issue to [OPO staff] as she would've liked to have seen KODA clinically rule this patient out prior to getting consent/giving this family another glimmer of hope in their otherwise grave circumstances . . . [case KYDA-332, 2023; GCS 8T, overbreathing the vent with all reflexes intact]

"[Physician] said that he wanted there to be a smoother process with assessing pt suitability with medical team before approaching family to prevent future events like this. I told him that we do our best to assess pts properly and every situation is different but we continue to try and make process better." [GCS 8T, 2023; GCS 8T, breathing without mechanical support for 72 hours prior to KYDA cancelling case]

Issues with recognition of high neurologic function

The most common concern found in the ANR cases was the failure to recognize preserved neurologic function that made successful DCD recovery unlikely. OPO records show numerous instances of discordant assessments, such as describing the GCS as 3T in patients with spontaneous eye opening – an impossible scenario, as the eye opening alone would mean a GCS of at least 6. Low GCS scores were documented on patients receiving three sedative drugs simultaneously, and with large and physiologically improbable swings in reported GCS over periods as short as 1-2 hours. In most cases, once authorization had been obtained and the coordinators' attention turned to perioperative logistics, there was scant subsequent recording of patients' clinical condition.

Lack of understanding or concern regarding the effects of medication on patients' neurologic status extended right up to the point of going to the operating room. For patient KYDA-312 in 2022, for example, anesthesia objected to allowing withdrawal of therapy because the patient was still chemically paralyzed. For KYDA-375 in 2023, the ICU attending physician stated that the patient would need 36 hours to fully clear sedation, yet the recovery went ahead only 6 hours later. And for patient KYDA-015 in 2024, a plan was entered to hold sedation and document findings, but the patient went to the operating room on the original schedule with no evidence this occurred. As described above, because the records submitted to HRSA are only those in whom there was not a rapid progression to cardiac death, HRSA cannot conclude whether the same pattern of withdrawing care in patients under chemical paralysis or sedation is at least as frequent among the patients who did progress to recovery as DCD donors.

Three cases in the years after the index patient's experience serve to illustrate the combination of clinical errors in judgment and management that have remained common in KYDA practice since the time of the index case reported to Congress:

Case KYDA-239 (December 2022)

This was a 50 year old male victim of unintentional overdose:

> "*At approximately the 50 minute mark, pt's alertness changed. The glazed over look in his eyes disappeared, and he began to look around. His eyes were watering, and he began to move around. The OR staff started talking to him to see if he would follow commands. At that time, he did not obey, but he was being purposeful and had some active reflexes*."

The recovery attempt was allowed to continue to the 90 minute mark, at which point the patient was brought back to the ICU.[33] He sat up and spoke with his family before passing away three days later. It is notable that the case had been delayed by four hours from its originally scheduled time. One explanation for the patient's sudden increase in sensorium would be that chemical sedation was wearing off. If this was the case, it is possible that this patient may have passed away and been recovered as a donor had the case occurred at the originally scheduled time.

An internal feedback document noted:

> "*Unfortunately, this left the patient in the situation of waking up, draped and prepped in an OR after he was extubated. After it was assessed that the patient was awake and following commands, KODA did not abort the DCD attempts, they held steady to the 90 minutes time frame. This was very uncomfortable for the nurse involved, because the patient had no idea what was going on but was becoming more aware by the minute*."

The corrective action plan, finalized six months later, included reference to only one meeting with hospital leadership, during which "*it was decided that there needed to be targeted education with the hospital staff on DCD processes. This education is ongoing*." There was no reference to internal education or discussion of OPO DCD protocols.

Case KYDA-363 (December 2023)

This was a 63 year old man with a history of polysubstance abuse, admitted after being found down. He had a GCS of 7 and intact reflexes and was overbreathing the ventilator on sedation. On the first night after the OPO took over the case, hospital staff were unable to locate the assigned KYDA coordinator. The OPO coordinator was ultimately discovered asleep in an unoccupied ICU bed, and was suspected by hospital nurses to have been intoxicated at the time. In response to a complaint from the hospital, the OPO "*stressed to the hospital that we do not allow staff to operate in this capacity and it was completely unacceptable*."

The following day, other OPO coordinators entered two notes documenting high neurologic status and improving respiratory drive in two separate exams, noting, "*[r]eviewed results with [supervisor], who stated that since pt is a GCS of 6 and it is not an oppositional case, the results indicating a high risk of continued breathing will not affect the progression of case per policy*." The GCS of 6 is documented as being assessed while the patient was receiving a continuous infusion of the drug propofol at a dose sufficient to produce complete sedation.

[33] KYDA routinely used 90 minutes as the upper limit of time in which a patient may pass away after withdrawal of life support and still be a solid organ donor. In this case, the OPO did not deviate from the planned 90 minutes despite clearly documented signs that the patient was aware and unlikely to pass in the designated time frame.

The next day, a second complaint was made from the hospital to the OPO, as they again could not locate the patient's assigned coordinator. In this case, the OPO staff member had left to be at home for the holiday, though "*[h]ospital staff stated that their main concern was that KODA staff was supposed to be onsite at all times during an active case*."

The following day, the patient was brought to the operating room for an attempted recovery. They passed four days after being extubated.

Case KYDA-307 (December 2024)

This is a 44 year old woman whose presenting neurologic insult is unclear due to the partial nature of records provided to HRSA by KYDA. The family is Spanish-speaking, and was described as distrustful of KYDA and first person authorization. After obtaining consent to proceed, KYDA staff documented the patient's neurologic status as GCS 5T on sedation. Four hours prior to the attempted recovery, a KYDA coordinator wrote "*[next of kin] requested that she did not want that MD increased more patient dose of sedation unless be necessary [sic] or use more sedation in any kind of procedure. She was very adament [sic] with sedation medication*."

When she was brought to the operating room, however, the recovering surgeon was alarmed by spontaneous eye opening, leg flexion, and arm movements. The surgeon estimated her GCS to be at least 8T, and after consulting with the center for whom he was recovering, he determined that he was not comfortable proceeding.

The amount of time spent by the patient in the operating room is unclear, but is at least 30-45 minutes based on the timeline of provided materials.

KYDA did not shut down the attempt until they had approval from their Medical Director, VP of Organ Operations, Director of Organ Operations, and Organ Operations supervisor. During one of the group phone calls related by staff, they noted:

> "*While on the call, writer heard [palliative care attending physician] state his frustration and claimed that he and his colleagues had reported to [KYDA] staff that this patient would not pass quickly and it would likely be days but more so likely to be weeks before she passes and they felt the patient was more suitable for palliative care*."

As of January 13, 2025, there was no cardiac time of death listed for this patient. Four days after the attempted recovery, KYDA received a complaint from the hospital stating:

> "*She has a concern about a coordinator with serious allegations and would like to speak to someone today regarding this. She said she has been trying to get into contact with someone for an hour so I just took her information and let her know someone would follow up with her*."

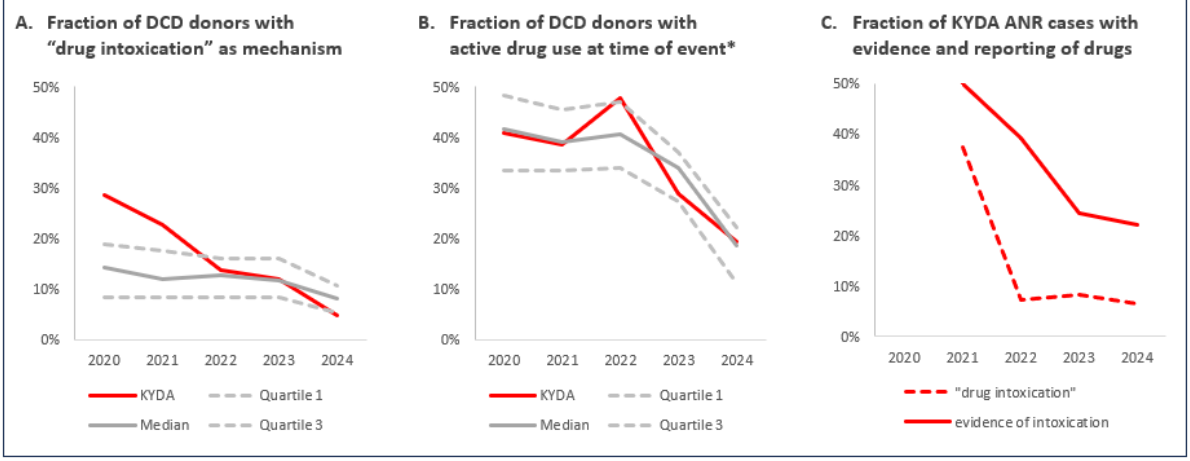
No further documentation on the nature of the complaint or its response was provided.

These cases demonstrate the potential danger of overlapping patterns of error in KYDA practice: when patients who are poorly suited to DCD recovery are under the care of providers with variable levels of professionalism, otherwise preventable instances of suffering for patients and family become frequent, if not inevitable.

Issues with recognition and documentation of drugs in patient records

Cases submitted by KYDA minimized the role of illicit drug use in patient histories. Among 351 cases with analyzed data, 28 (8.0%) were reported as having drug intoxication as their mechanism of death. Review of material in the submitted records shows that KYDA staff would have known that the number of cases occurring as a result of intoxication with opioids, amphetamines, or cocaine is at least 98 patients (27.9% of the total volume).[34] At a minimum, KYDA failed to accurately document the etiology of patients' injury in 70 out of 98 drug overdose cases reviewed (failing to report drug-related etiology for 71% of patients).

Figure 7: Documentation of drug intoxication in donor and ANR patient records. (A) and (B), OPTN data on KYDA vs. other OPOs. (C) KYDA ANR records: "drug intoxication" vs evidence in history, toxicology report or DRAI of active drug use.
** Note: OPTN data reporting on active drug use changes in 9/2023, with increased missingness in 2023 and 2024.*



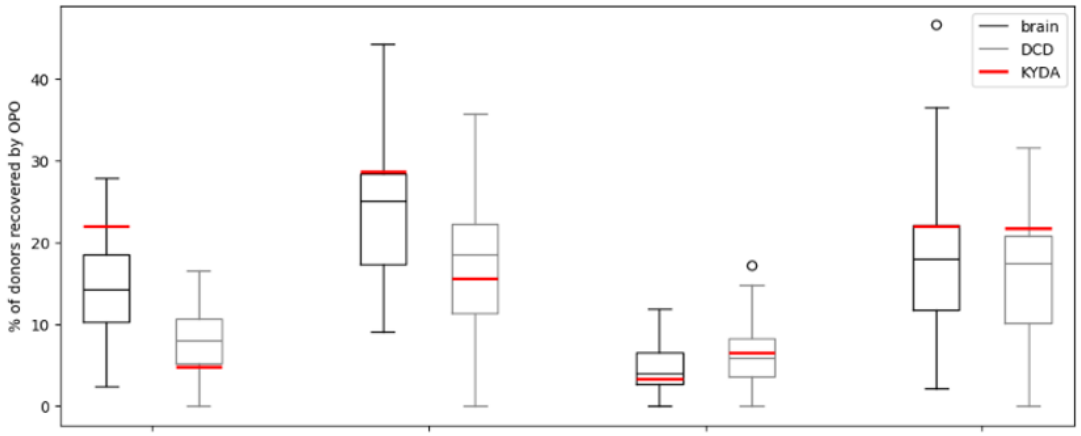
Variable and misleading reporting of drug overdose as donors' mechanism of death in OPTN data has previously been documented.[35] The physiologic effects of these drugs can include death through cardiovascular collapse, asphyxiation, anoxia, or event traumatic injury in the event of intoxication. As shown in **Figure 7**, KYDA data have historically failed to capture the impact of drugs on the DCD patient population. Of note, OPTN data reporting changed in September 2023, with data entry now requiring additional and precise documentation of "date of last use" of drugs.

[34] This is a conservative estimate, as it is based on documentation in OPO staff notes, patient toxicology reports, and family reporting of active drug use at the time of the patient's presentation. Records provided to HRSA included fewer of these chart elements for later years of the submitted era.
[35] Goldberg D, Lynch R. Clin Transplant 2020 34(1):e13755.

Figure 8 shows data for the first full year of OPTN data reporting with the new drug codes. As shown, there is a high degree of missingness in the variable that establishes active drug use at the time of the patient's neurologic injury. This missingness is likely related to the new variable being a free text field, so that OPO users are not required to select a value in order to complete data entry. Inthis setting, it is possible that reporting bias is contributing to inaccurate information on the degree to which drugs play a role in donor patients' demise. As illustrated, for DCD patients, KYDA reports below-median rates of "drug intoxication" as a mechanism of death and has below-median evidence of active drug use for DCD donors. The validity of these data is questionable, however, as KYDA's missingness for drug history is above-median, and missingness for time of last use is at the 82nd percentile nationwide.

This issue is of relevance to the current investigation because patients in a DCD pathway may be having their true neurologic condition masked by ongoing physiologic effects of drug intoxication. As opposed to brain dead donors, in which physiologic or chemical confounders of suppressed mental status must be ruled out prior to establishing a brain death diagnosis, there is no such standard for DCD evaluation.[36] **Twenty of the ANR cases reviewed by HRSA, including that of the index patient, involved failure to recognize high neurologic function in a victim of drug intoxication. In 15 (75%) of those cases, the OPO failed to document the patient's correct mechanism of death.** As above, these numbers and rates are conservative estimates given the incomplete nature of the OPO charts.

Figure 8: 2024 OPTN data related to drug use at time of presentation for DCD and brain dead donors



[36] Greer DM, Kirschen MP, Lewis A, et al. (2023) Neurology 101(24):1112-1132.

SUMMARY OF HRSA FINDINGS

In summary, this review suggests that KYDA has engaged in a pattern of concerning DCD practices that expose patients to risk of preventable harm and potentially unsafe conditions. This issue is important to address because as many as two thirds of patients with whom KYDA interacts as potential donors are encountered through the DCD pathway. Beyond the concerning patient-level interactions, KYDA has also failed to accurately report relevant data to the OPTN, has sought to minimize to the OPTN and HRSA the degree and type of errors in the case of patient KYDA-001, and is alleged to have retaliated against a Congressional whistleblower.

The history of this case also suggests that the OPTN has not adequately surveilled for and addressed clinical risks at KYDA. The MPSC closed its initial investigation without any review of source materials it had requested, though the OPTN contractor repeatedly claimed otherwise to the Board of Directors.[37] OPTN and UNOS leadership signed on to a letter condemning oversight activities and citing KYDA-001's case as an example of misinformation and hearsay. After a four month investigation, the OPTN failed to identify patterns of unsafe care, connect KYDA practice decisions with observed outcomes, or make specific recommendations to prevent further harm. This report recommends that HRSA take additional action to ensure patient safety and protect public confidence in the integrity and security of the US organ procurement and transplant system.

RELEVANCE TO OTHER POLICY AND PRACTICE CONCERNS

- HRSA is engaged with the OPTN on a critical comment process regarding normothermic regional perfusion (NRP). In the process of that review, HRSA has uncovered concern among transplant providers and the international transplant community that high neurologic function patients in the DCD pathway are the most at risk for harm from cerebral perfusion.[38]

- In December 2024, the OPTN OPO Committee has established a Donation after Circulatory Death Policy Review Workgroup, with a goal being to "ensure that DCD policies are relevant and aligned with current practice." In workgroup meetings in December and January, this group has emphasized the need to move OPO communication with the patient's family earlier in the course of care:
    - The workgroup seeks to 'revisit' the current timeline in how early OPOs bring up the DCD option to families of neurologically injured patients (as per OPTN Policy 2.15):"*Prior to the OPO initiating any discussion with the legal next-of-kin about organ donation for a potential DCD donor, the OPO must confirm that the legal next-of-kin has elected to withdraw life sustaining medical treatment."*

[37] In the February 27 Board meeting, UNOS staff stated "so, MPSC did review the index case and we can provide a summary." On March 3, UNOS provided a written document to the Board claiming that documents were reviewed by MPSC in response to the 9/12/2024 letter. This claim is not supported by the materials submitted by KYDA at the time or contemporaneous notes from HRSA personnel who attended the 9/20/2024 MPSC meeting.
[38] Domínguez-Gil B, Miñambres E, Pérez-Blanco A, et al. Transplantation (2025)

- An ethicist on the workgroup (Dr. Robert Truog) with a long history of input on donation and procurement is on the workgroup, and his comments in the January 22 meeting are concerning (emphasis added): *"But I worry a little bit that, you know, we not look at this as 'well, current practices are that we're not really respecting that firewall [between what is in the best interest of the patient and what is in the interests of procurement] anymore, you know, we're already sort of broaching that, and so, since we are already doing that, we should change the policy.' I think that gets it a little bit backwards; I think that we should first of all make a decision as to whether the policy needs to be changed at this point, and then secondary to that would be how that would take place and what the new policies would be . . .* ***and I recognize that, you know, look, at my, you know being a little bit of a naysayer here to, what I sense is the momentum of this committee****."*

- HRSA notes that an unknown fraction of DCD potential patients may be moved to OPO-controlled organ recovery facilities that have fewer safeguards, no mechanism for oversight in the form of conditions or standards from CMS, nor currently defined survey or certification processes.[39,40]

Cumulatively, these separate trends require robust processes and monitoring to protect patients and preserve transparency and trust in the DCD procurement pathway.

[39] Marklin GF, Brockmeier D, Spector K (2023) Am J Transplant 23(7):891–903.
[40] See: "Exploring NRP and DCD Recovery Units to Improve Kidney Utilization," End Stage Renal Disease Trea tment Choice Learning Collaborative (ETCLC) public presentation, 1/15/2025.

APPENDIX I: OPTN FINDINGS OF HRSA-DIRECTED INVESTIGATION

OPTN

Findings of the HRSA-Directed Investigation of Network for Hope

Richard Formica, M.D., President, OPTN Board of Directors
March 4, 2025

Executive Summary

The Organ Procurement and Transplantation Network (OPTN) conducted a review of Network for Hope (KYDA) to assess potential risks to patient safety after an alleged patient safety incident was recounted during a government hearing, as well as related media reports and community concerns. This review focused on KYDA's standard operating procedures (SOP), quality assurance activities, and safety monitoring related to patients who were evaluated for potential Donation after Circulatory Death (DCD) procurement.

A team of OPTN Board of Director and OPTN Committee volunteers, representing expertise in OPO operations, normothermic regional perfusion and DCD operations, reviewed documents submitted by KYDA in response to the investigation. The team reviewed donor and patient records, process and protocol documents, and pre-withdrawal huddle records.

After reviewing the documentation, the team concluded that cases and processes were well documented, including conversations with families, case touchpoints, staff time, and rationale for decisions. Reviewers noted opportunities for improvement including the lack of a surgical coverage plan, and suggested KYDA may want to more thoroughly assess donor suitability prior to approaching families but overall noted no major patient safety concerns based on their review.

Background

HRSA directed the OPTN, with support from the OPTN contractor, to conduct a review for potential risks to patient safety from organ procurement activities performed by OPTN member KYDA, the organ procurement organization (OPO) serving Kentucky and select counties in Ohio, West Virginia, and Indiana. This direction was based on the alleged patient safety incident described in the September 11, 2024, House Energy and Commerce Committee hearing[1], additional media reporting[2,3], and concerns received from the community, with the goal of ensuring the safety and integrity of the national procurement and transplantation system.

HRSA directed the OPTN to review KYDA's organ procurement process, with particular focus on patients who were evaluated by KYDA for potential DCD procurement. The review focused on KYDA's standard operating procedures, quality assurance activities, and safety monitoring for patients identified for potential DCD organ procurement.

HRSA requested the following information:

1) Donor-specific documentation

[1] https://energycommerce.house.gov/events/oversight-and-investigations-subcommittee-hearing-a-year-removed-oversight-of-securing-the-u-s-organ-procurement-and-transplantation-network-act-implementation
[2] https://www.npr.org/sections/shots-health-news/2024/10/16/nx-s1-5113976/organ-transplantion-mistake-brain-dead-surgery-still-alive
[3] https://richmond.com/news/local/business/health-care/kentucky-organ-recovery-group-accused-of-pursuing-transplant-before-patient-died/article_0e5b48ee-7062-11ef-9384-43d79b59013d.html

a. From KYDA – all donor and medical records and documentation, list of all procurement staff scheduled each day, records and/or transcripts of all calls between procurement and Baptist Health Richmond staff, exit interviews for KYDA staff if departed due to incident, signed non-disclosure agreements for staff departed due to incident, documentation of any after-action reviews taken by KYDA in response to incident
b. From the OPTN – complete OPTN Computer System donor record including documents and images, all match run data and potential transplant recipient data associated with the donor

2) Baptist Health Richmond Hospital related documentation
   a. KYDA-Baptist Health Richmond agreement, both on incident date and currently in effect
   b. KYDA-Baptist Health Richmond case rates and descriptions of services for patients who have potential to become DCD organ donors, both on incident date and currently in effect
3) All hospitals in KYDA Donor Service Area related documentation
   a. All KYDA DCD pathway organ procurement SOPs regarding location and protocols in effect at any point since incident
   b. All records relating to patient cases since incident in which a patient was followed by KYDA for DCD-potential organ procurement that terminated with an extubation of the patient without a cardiac time of death
   c. All records relating to the occurrence and content of any pre-withdrawal calls (huddles) to discuss withdrawal procedure, medications or comfort care, pronouncement, roles and prohibitions-of-roles for hospital, OPO, and transplant center/procuring staff
   d. Any documented deviations from the required protocols or huddles for each listed case
   e. Any event-specific feedback sought or received from the donor hospital staff and/or hospital leadership following the withdrawal regarding each listed case
   f. Any event-specific feedback sought or received from the procuring transplant center staff and/or procuring transplant center leadership following the withdrawal regarding each listed case

Reviewer Team

A team of OPTN volunteers was assembled to assess KYDA patient safety, quality assurance, and operational compliance with requirements in OPTN Bylaws, Policies and Obligations for patients with potential to become DCD organ donors. The team represented experience in OPO operations, normothermic regional perfusion/DCD operations, or both. The team included members from the OPTN Board of Directors, the OPTN Membership & Professional Standards Committee (MPSC), and the OPTN Operations & Safety Committee. This was inclusive of a living donor and a transplant recipient who is also a donor family member. The reviewers were assessed for and identified as free of conflicts of interest.

Name	OPTN Role	Organization	OPTN Region
Kristine Browning	MPSC At Large	VP of Quality & Regulatory Compliance, LifeGift Organ Donation Center	Region 4
Chad Denlinger	MPSC At Large	Transplant Surgeon, Indiana University Health	Region 10
Glen Kelley	OPTN Board of Directors, transplant recipient, donor family	The Mended Hearts, Inc.	Region 3

Kyle Herber	MPSC At Large	President & CEO, Live On Nebraska	Region 8
Luis Mayen	MPSC Region 5 representative, living donor	VP of Strategic Partnerships & Business Development, Donor Network West	Region 10
Debbi McRann	MPSC Region 2 representative	VP & Chief Clinical Officer, Infinite Legacy	Region 2
Steve Potter	Operations & Safety Committee Vice Chair	Transplant Surgeon, Medstar Georgetown Transplant Institute	Region 2
Zoe Stewart Lewis	MPSC Ex Officio	Transplant Institute Director, University Hospitals of Cleveland	Region 10

Focus of Review

The reviewers focused on the following areas:

- Was there authorization and consent for potential DCD procurement?
- Did KYDA conduct their pre-withdrawal huddles?
  - If yes, were all the necessary participants involved?
  - Were key aspects such as roles, medications, and device usage clearly discussed and documented?
  - Did KYDA provide a rationale for any missed pre-withdrawal huddles?
- Did KYDA uphold patient safety protocols from approach through donation?
- Did KYDA follow their own policies and procedures?
  - Were withdrawal procedures followed as specified?
  - Did KYDA conduct a post-procedure review to ensure adherence to protocols?
  - Were there any deviations from standard procedures, and if so, were these justified and documented?
  - Did KYDA obtain and document all OPTN-required consents?
  - Was all required testing completed before procurement?
  - Did KYDA adhere to all OPTN obligations and timelines throughout the process?

Records Reviewed

The reviewers were provided with documents collected by the OPTN Contractor, as directed, from KYDA including:

- Donor and patient records: patient case records for DCD-potential organ procurement that terminated with an extubation of the patient without a cardiac time of death, including any deviations in SOPs and case feedback from the donor hospital
- Process and protocol documents: SOPs and protocols for DCD pathway organ procurement
- Huddle records: records relating to the occurrence and content of any pre-withdrawal calls

Below is a summary of the type and number of records received and reviewed:

Document Type	Received	Reviewed	Not Reviewed
Donor and Patient Records	362	315	47
Process and Protocol Documents	34	18	16
Huddle Records	59	43	16

Reviewer Findings
The reviewers would like to commend KYDA on their support for patient families, particularly through complex DCD cases and those that may not result in donation. Cases and processes were well documented, including conversations with families, case touchpoints, staff time, and rationale for decisions. Additionally, the OPO's structured approach to involving medical directors and administrators when issues arose was commended.

Overall, there were no major concerns or patterns identified. While no major issues were found, reviewers pointed out a few small areas of improvement. Reviewers observed that there seemed to be a lack of surgical coverage plans, which led to OR delays. Concerns were raised about recurring delays due to a lack of surgeon coverage, impacting families waiting in the OR. Reviewers also noted that KYDA may want to assess donor suitability more thoroughly before approaching families. It was noted that the Five-Minute Observation Rule was not observed in two cases.

Next Steps
Additional steps, including the potential for a directed peer visit to the OPO, will be determined after the requested information is reviewed by the OPTN and HRSA.

Board Findings
The OPTN Board convened on February 27 and March 3, 2025, to review key findings of the OPTN investigation.

After review, the Board voted on March 3, 2025, on the following recommendation:

"The OPTN recommends the Secretary (1) require KYDA to perform a root cause analysis of KYDA's failure to adhere to its own policies, including, but not limited to, failure to comply with the Five Minute Observation Rule, (2) require KYDA to develop and adhere to a KYDA policy that clarifies who is a suitable candidate as a DCD donor, and (3) require KYDA to develop a policy that allows any individual to stop progression of a donation if they identify a patient safety issue."

The voting outcome was as follows: Affirm – 25, Oppose – 1.

HRSA
Health Resources & Services Administration
Health Systems Bureau/Division of Transplantation
5600 Fishers Lane
Rockville, MD 20857

May 28, 2025

Richard N. Formica, Jr., MD
President, Board of Directors
Organ Procurement and Transplantation Network
[redacted]

Rexanah Wyse Morrissette, Esq.
Interim Executive Director
Organ Procurement and Transplantation Network
[redacted]

Dear Dr. Formica and Ms. Wyse Morrissette:

The Health Resources and Services Administration (HRSA) has considered the Organ Procurement and Transplantation Network's (OPTN) recommendations in regard to organ procurement care provided by Network for Hope (OPTN code: KYDA), the organ procurement organization (OPO) serving Kentucky, southwest Ohio, and part of West Virginia. On October 18, 2024, HRSA directed the OPTN to undertake this special review based on authority granted by the final rule governing the operation of the OPTN (OPTN Final Rule) as described in 42 CFR 121.10(b)(3):

> *At the request of the Secretary, the OPTN shall conduct special reviews of OPOs and transplant programs, where the Secretary has reason to believe that such entities may not be in compliance with these rules or OPTN policies or may be acting in a manner which poses a risk to the health of patients or to public safety.*

In parallel with the OPTN's special review, HRSA has undertaken its own review of KYDA under the authority described in 42 CFR 121.10(a) (emphasis added):

> ***Review and evaluation by the Secretary.*** *The Secretary or her/his designee may perform any reviews and evaluations of member OPOs and transplant programs which the Secretary deems necessary to carry out her/his responsibilities under the Public Health Service Act and the Social Security Act.*

Background

The impetus for the OPTN and HRSA investigations was an allegation of potentially preventable harm to a neurologically injured patient in KYDA's donor service area (DSA) in 2021. The allegation was made in the form of a letter discussed at a Congressional hearing on September 11, 2024. On September 12, 2024 the OPTN Membership and Professional Standards Committee

(MPSC) sent a letter to KYDA requesting details of the case, including documents from the patient's electronic medical record (EMR) maintained by the OPO and results of any root cause analyses performed with regard to the case. KYDA replied to this request on September 20, 2024 with a letter clarifying that the case was not one involving brain death, but rather donation after circulatory death (DCD) procurement. The reply did not include the patient-level materials or administrative documents requested by the MPSC. On September 24, 2024, the MPSC closed the case without further action.

On October 1, HRSA directed the OPTN to reopen the investigation and reiterate the request for documents. On October 7, 2024, KYDA returned documents that had been requested by the OPTN in the September 12, 2024 letter. On the basis of these materials, HRSA directed the OPTN to request additional medical records from KYDA, with the period of review covering October 2021 through December 2024. Due to concerns regarding the MPSC's inadequate prior response, HRSA directed the OPTN to empanel an ad hoc review group to examine KYDA records provided[1] for the special review. On February 27 and March 3, 2025, the OPTN Board of Directors convened to discuss the findings of the special review.

Findings of the OPTN Special Review

The OPTN's report in response to the special review of KYDA is attached as Appendix I. The OPTN's final four page report stated, "[*O*]*verall, there were no major concerns or patterns identified. While no major issues were found, reviewers pointed out a few small areas of improvement*."[2] Specific points for improvement included a recommendation to improve surgical coverage to minimize alleged delays, and potentially premature contact with to patient families to request organs prior to assessment of the patient's suitability for donation. Following discussion of potential compliance options, the OPTN Board of Directors voted to make the following recommendation to the Secretary regarding KYDA:

> "*The OPTN recommends the Secretary (1) require KYDA to perform a root cause analysis of KYDA's failure to adhere to its own policies, including, but not limited to, failure to comply with the Five Minute Observation Rule, (2) require KYDA to develop and adhere to a KYDA policy that clarifies who is a suitable candidate as a DCD donor, and (3) require KYDA to develop a policy that allows any individual to stop progression of a donation if they identify a patient safety issue*."

Findings of the HRSA Review

Between December 1, 2024 and February 28, 2025, HRSA reviewed the complete set of OPO EMR documents for 351 unique patients for whom organ donation was attempted by KYDA but from whom organs were not procured (generally referred to by the organ procurement industry as "authorized not recovered" or ANR patients). In addition, HRSA reviewed documents regarding hospital development and corrective action reports in response to KYDA-identified

[1] HRSA notes that the empaneled committee did not complete review of 47 (13% of total) cases.
[2] "Findings of the HRSA-Directed Investigation of Network for Hope," report to OPTN Board of Directors, 3/4/2025.

adverse events. In contrast to the OPTN report of its special review, HRSA found a concerning pattern of risk to neurologically injured patients in KYDA's DSA stemming from KYDA staff practices. These included:

1. Inconsistent assessment and re-assessment of patient neurologic function to detect changes that could be inconsistent with or unfavorable to DCD organ recovery. *Multiple patients were documented as evincing pain or discomfort during peri-procurement events after OPO staff had either failed to adequately assess neurologic function in the setting of sedation or chemical paralysis, or had documented findings inconsistent with successful DCD recovery without change to the plan for procurement.*

2. Inconsistent coordination of care with patients' primary medical teams, including a lack of clarity in the roles of OPO staff and healthcare teams in patient care. *OPO records document instances of OPO staff preempting healthcare teams' concerns about planned care.*

3. Inconsistent attention to independent decision-making authority of legal next of kin. *OPO records document OPO staff approaching potential donors' family members that they believed to be under the influence of illicit substances or lacking cognitive capacity to understand their role in the decision to donate..*

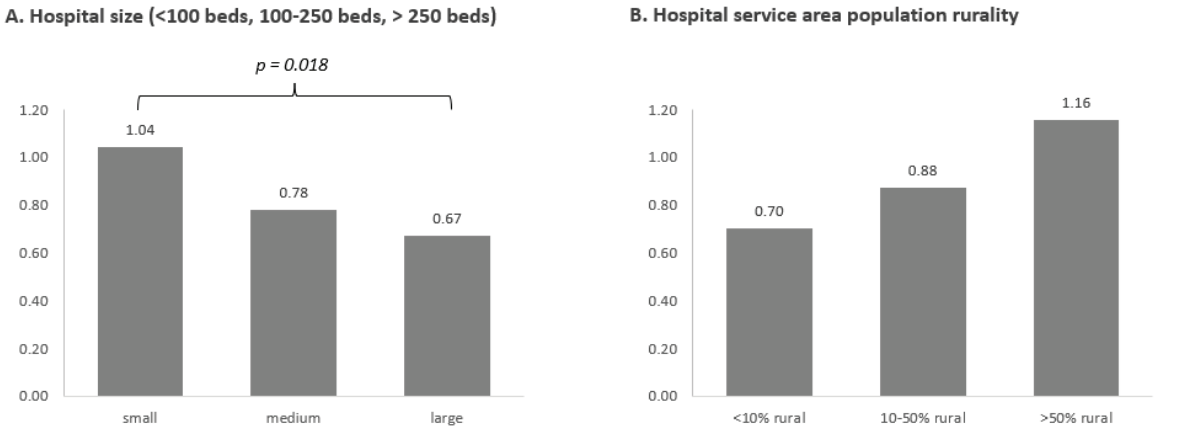
4. Inconsistent collection and coding of patients' medical data, as outlined in OPTN policies,[3] professional best practices[4] as well as internal policies and guidelines. *A high proportion of patients for whom the OPO's records show evidence of drug overdose or intoxication were described as having mechanisms of death other than drug-related.*

HRSA's review found 103 ANR cases (29.3%) with concerning features, including 73 patients (20.8%) for whom either the initial or subsequent neurologic status showed features not conducive to DCD procurement. At least 28 (8.0%) patients had no cardiac time of death noted, suggesting potential survival to hospital discharge.[5]

The records HRSA reviewed suggest that patients may experience variable care from KYDA depending on the hospital in which they are seen. There was a higher frequency of ANR cases relative to total DCD procurements at smaller hospitals and hospitals serving more rural populations (Figure 1).

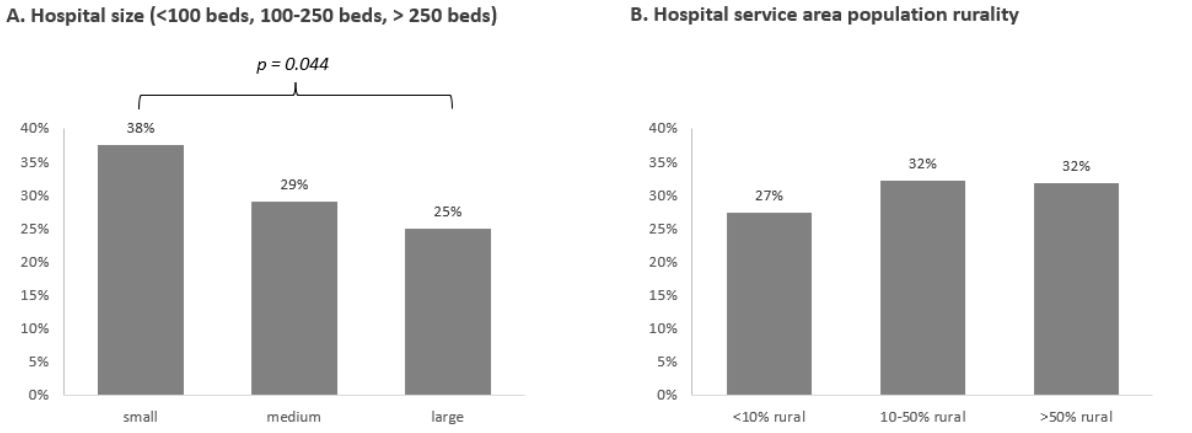
[3] See: OPTN Policies 2.3, 2.11.
[4] Association of Organ Procurement Organizations (AOPO) Standards & Interpretive Guidelines, 2020, CL-4B.
[5] See: 42 CFR 486.328(a) *Condition: Reporting of Data* for requirements regarding the "number of deaths" and "data related to the non-recovery of organs" for which cardiac time of death would generally be collected and noted by the OPO for authorized, but not procured, patients.

Figure 1: Authorized, not recovered (ANR) cases per DCD donor, by hospital characteristic within KYDA DSA 2021-2024



The fraction of ANR cases with concerning clinical features also varied by hospital size and patient population (Figure 2).

Figure 2: Fraction of ANR cases with concerning features by hospital characteristic with KYDA DSA, 2021-2024



Cases submitted by KYDA consistently misreported the role of illicit drug use in patient histories. Among the 351 cases reviewed by HRSA, 28 (8.0%) were reported as having drug intoxication as their mechanism of death. Review of material entered by KYDA staff into their EMR shows that OPO staff had information showing that 98 (27.9%) of ANR cases showed the terminal admission and neurologic insult to be related to active use of opioids, amphetamines, or cocaine at the time of their injury.[6] Stated another way, KYDA did not document drug overdose

[6] This is a conservative estimate, as it is based on documentation in OPO staff notes, patient toxicology reports, and family reporting of active drug use at the time of the patient's presentation. Records provided to HRSA trended toward lesser inclusion of these chart elements in 2023 and 2024, so the fraction of cases with missed drug intoxication as a cause may be higher than reported.

as the mechanism of death in approximately three out of four patients with evidence of drug intoxication from the sample HRSA reviewed.

The miscoding or lack of recognition of drug intoxication is of relevance because patients in a DCD pathway may be at higher risk of their neurologic condition being masked by ongoing psychoactive effects of drug intoxication. As opposed to brain dead donors, in which physiologic or chemical confounders of suppressed mental status must be ruled out prior to establishing a brain death diagnosis, there is no such standard for DCD evaluation.[7] The risk for potential-DCD patients is that depressed mental status may be ascribed to a permanent and irreversible injury, rather than slow clearance of the effects of chemical intoxication. Twenty of the ANR cases reviewed by HRSA, including that of the index patient, involved failure to recognize high neurologic function in a victim of drug intoxication. In 15 (75%) of those cases, the OPO's documented mechanism of death did not reflect overdose as the inciting event for the neurologic injury. As above, these numbers and rates are conservative estimates given the incomplete nature of the OPO charts.[6]

The prevalence of these patient-level issues suggests systemic concerns regarding the treatment of potential DCD donor patients by KYDA staff. HRSA's review indicates the potential for ongoing risk of harm to patients in KYDA's DSA, as cases similar to the 2021 index case were found to have occurred as recently as December 2024.

Corrective actions

Action to address care by KYDA that presents potential risk to public health and patient safety and provide objective and transparent oversight of all OPOs is central to HRSA's regulatory role and the aims of the OPTN Modernization Initiative, as it serves to measurably improve accountability, fairness, and performance within the national organ procurement and transplant system.[8] HRSA has considered the OPTN's report of its special review of KYDA, in conjunction with HRSA's findings of its own review of KYDA records. As per the OPTN Final Rule:

> *"[t]he Board of Directors shall advise the Secretary of the results of any reviews and evaluations conducted under . . . paragraph(b)(3) of this section [relating to Secretary-directed OPTN special reviews] which, in the opinion of the Board, indicate noncompliance with these rules or OPTN policies, or indicate a risk to the health of patients or to the public safety, and shall provide any recommendations for appropriate action by the Secretary*"; and *"[u]pon the Secretary's review of the Board of Directors' recommendations, the Secretary may . . . take such other action as the Secretary deems necessary*."[9]

Pursuant to these authorities, this letter directs the OPTN to take the following actions:

[7] Greer DM, Kirschen MP, Lewis A, et al. (2023) Neurology 101(24):1112-1132.
[8] HRSA OPTN Modernization Initiative announcement, 3/22/2023.
[9] See: 42 CFR 121.10 (c).

(A) Within 30 days, develop and implement a 12-month OPTN MPSC monitoring plan for KYDA to address the concerns identified in the OPTN and HRSA reviews, including improved documentation of patient neurologic status. Reliability, completeness, and timing of neurologic assessment by KYDA should be the highest priority. At a minimum, the monitoring plan should address the following areas:

1. Just-in-time pre-procurement education with hospital operating room staff about anticipated possible outcomes from DCD procurements with patient-specific information including accurate neurologic status.

2. Neurologic assessments at a minimum frequency of every twelve hours from initial assessment until case end, either by organ recovery, cardiac time of death without organ recovery, or case closure. Assessments should include:
    a. Total and component (eye, motor, verbal) Glascow Coma Scale (GCS)
    b. Brain stem reflexes (cough, gag, corneal, pupillary)
    c. Respiratory effort, including ventilator settings and mandatory and patient-initiated breath rates
    d. Patient sedative history, including current infusions and injections of narcotic, sedative, or other psychoactive medications in the six hours preceding exam
    e. Presence or absence of pathologic or pharmacologic paralysis
    f. Evidence or suspicion of reversible encephalopathy from infection, uremia, drug withdrawal or metabolic source

3. Consultation with the primary healthcare team regarding any potential risk or concern that the patient has not metabolically cleared any illicit psychoactive drugs, and document such assessment.

4. Documentation for all paralytic and psychoactive medications administered in conjunction with withdrawal of life support, with documentation beginning six hours prior to extubation or other withdrawal of support through either cardiac time of death or termination of the procurement attempt.

Failure to comply with corrective action requirements as described above will prompt review by the Secretary for further actions to protect patient safety and public health in the KYDA DSA.

Since the review of KYDA was initiated, HRSA has received reports of similar patterns of high risk DCD procurement practices at multiple other OPOs. While reviews of these individual events and OPOs are ongoing, the high frequency of DCD procurement and concern for variation in the quality and safety of care across the country merit immediate development of minimum safety standards for the protection of neurologically injured patients being assessed as potential DCD donors. Therefore, the Secretary directs the OPTN to:

(B) Within 180 days, propose policies for public comment to improve safeguards for potential DCD patients in the organ procurement process and increase information shared with patient

families regarding DCD organ procurement. At a minimum, the proposed policies should address:

1. The process by which a "pause" in procurement efforts can be undertaken if there is concern for unrecognized neurological improvement or potential for a patient to experience pain in the act of procuring organs, including:
    a. A process for informing all stakeholders, including patient family, hospital staff, transplant center staff, and third party procurement and preservation staff that they empowered to call for a pause on procurement efforts if they believe the patient is experiencing increased neurological function or is at risk of experiencing pain during a procurement attempt.
    b. Any automatic triggers for a pause in procurement efforts if the patient shows objective signs of improving neurologic status. Potential triggers could include changes in brain stem reflexes, change or minimum threshold for GCS, or planned DCD procurement in the setting of self-determined withdrawal of care.
    c. Requirements for informing legal next of kin (LNOK), primary healthcare team, hospital leadership team, and any transplant centers with provisional acceptances if a pause in DCD organ procurement is triggered or requested.
    d. In cases where a pause is triggered or requested, requirements for the OPO to fulfill prior to resuming procurement efforts, such as convening with LNOK and primary healthcare team to discuss the patient's suitability for continued procurement efforts.
    e. In cases where procurement efforts are resumed after a pause has been triggered and discussed, the OPO must:
        1. Obtain acknowledgement from all transplant teams and their contracted representatives (i.e. procurement and preservation contractors) that they are aware of the pause and its resolution prior to the surgical procedure
        2. Inform the OPTN and HRSA of the case's resumption and subsequently provide further medical records to document case outcome.
    f. Data that should be collected regarding any "pauses" in procurement attempts. Data should be captured in the OPTN Deceased Donor Registration (DDR) Form or OMB-approved DDR replacement instrument. Each proposed field for data collection should be named and defined.
    g. A requirement for the OPTN to be informed within 24 hours of any requested or triggered pause, including specific data elements or records that should be included in the notification. MPSC will review the cadence and outcome of pauses during regular monthly meetings.

2. Requirements for family information about DCD organ procurement to be provided at the time of organ donation authorization. This education should include descriptions of any actions to be taken by the hospital and OPO should the patient not expire within the operative time limit or if organ procurement attempts are aborted in the operating room. HRSA understands this education is prevalent among OPOs, but the content and scope of

this education is variable and not defined in policy.[10] The OPTN should define what elements must be included in this education, and should involve the OPO, Ethics, and Patient Affairs Committees and donor, family, and patient representatives from the community to ensure the patient views are central to the proposed policy requirements.

3. An addition to OPTN Policy 2.2 that describes the OPO's responsibility to ensure that the patient family, hospital staff, transplant center staff, and third party procurement and preservation staff are empowered to call for a "pause" on procurement efforts if they believe the patient is experiencing increased neurological function or is at risk of experiencing pain during a procurement attempt to comport with the proposed policy described in this letter at (B)(1)(a), above.

4. An addition to OPTN Policy 2.2 that describes the OPO's responsibility to ensure accuracy in neurological assessment and appropriate neurological re-assessments to comport with the proposed policy described in this letter at (B)(1)(b), above.

5. For the policies proposed in (B)(1)–(4), above, the OPTN should include language that will solicit public comment regarding whether the proposed OPTN policies should be approved by the Secretary and made enforceable by HHS, in accordance with the process outlined in the OPTN regulations at 42 CFR 121.4(b)(2) and (c).

HRSA appreciates the work of the OPTN on behalf of patients, and we look forward to a collaborative relationship in enacting these needed safety reforms. If the OPTN has questions about the directives contained in this letter, HRSA staff are available for discussion and support. Please send the OPTN's response to the directives in parts A and B, above, by the dates indicated. Given that my role as HRSA's Health Systems Bureau Associate Administrator is one of oversight, on behalf of the Secretary, I will review the OPTN's response considering the requirements of NOTA and the OPTN Final Rule.

Sincerely,

Suma Nair -S Digitally signed by Suma Nair -S Date: 2025.05.28 11:25:01 -04'00'

Suma Nair, PhD, MS, RD
Associate Administrator

Cc: Christine Jones, MPH
Project Director, American Institutes for Research
[redacted]

Maureen McBride, PhD
CEO, United Network for Organ Sharing
[redacted]

[10] See Association of Organ Procurement Organization (AOPO) Standards and Interpretive Guidelines, January 2020, sections CL 11.2-11.3. https://aopo.org/wp-content/uploads/AOPO-Standards-Interpretive-Guidlines_January-2020_Final.pdf

UNOS

26 OPOs join new UNOS-led collaborative to increase DCD donor recoveries

Apr 13, 2021 | Collaborative improvement, News, OPO

UNOS is leading a national collaborative improvement project to support organ procurement organizations (OPOs) in increasing recovery of donation after circulatory death (DCD) organs. The project was launched by the Organ Procurement and Transplantation Network in October 2020, and involves 26 OPOs.*

The number of DCD organs recovered annually has steadily increased over the past decade, with 2020 exceeding 2019's record-setting numbers by more than 18 percent—extraordinary work during a pandemic year that saw large-scale disruption for OPO staff on the front lines of organ recovery. But there is more work to do.

"Being able to increase the number of donors means that more families are able to share the gift of life. OPOs do an amazing job honoring donor families, it's what drives them to continuously improve."

Beth Overacre, UNOS performance improvement lead

"This project's focus on the recovery of DCD organs highlights the continuing efforts of UNOS and the OPTN to support continuous improvement through sharing of effective practices in the OPO community," says Henrisa Tosoc-Haskell, UNOS senior director of organizational excellence. "Although there has been steady increase overall in the recovery of DCD organs, we know there is still an opportunity to do better and drive more transplants."

All teach, all share, all learn: Collaborating to increase organ recoveries

Collaborative improvement methodology, with its "all teach, all share, all learn" approach, allows participants to track progress and share key learnings in a supportive environment. The DCD procurement collaborative improvement project has drawn nearly half of the nation's 57 OPOs, who are participating in order to build on these performance improvement trends and increase

transplants. Coached by UNOS specialists, they are working to improve their organizational processes, become more efficient and save more lives.

Glenda Bronner, UNOS performance improvement specialist, says that because the project has drawn such a variety of participants, there is always something new for someone to learn. "Many of the participating OPOs have been working on this for quite some time, so it's been helpful for other programs who are just beginning this work." Having a mix of programs with different volumes has been an important element of the collaborative, and Bronner says the group is keen on sharing resources with each other: "they are proactively looking for new ways to improve and adapt their processes."

The 26 participating OPOs are in the project's active deployment phase through June of this year, and have access to a private project platform and an improvement guide. Data will continue to be collected and analyzed through the end of the year. Overall, the collaborative aims to increase DCD donor recovery 20 percent from 2020 to 2021, with every OPO setting their individual aim, from 5 percent to 40 percent.

Beth Overacre, UNOS performance improvement lead, says increasing recovery of DCD organs has an immediate impact on transplant candidates, because it increases organs for transplant, but the effect on donor families is also significant and something that motivates participants. "Being able to increase the number of donors means that more families are able to share the gift of life. OPOs do an amazing job honoring donor families, it's what drives them to continuously improve."

The participating OPOs include:

- Arkansas Regional Organ Recovery Agency
- Carolina Donor Services
- Donor Alliance
- Donor Network of Arizona
- Gift of Life
- Iowa Donor Services
- Legacy of Hope
- Legacy of Life Hawaii
- LifeCenter Northwest

- LifeGift
- Lifeline of Ohio
- LifeLink of Florida
- LifeShare Carolinas
- LifeShare Transplant Donor Services of Oklahoma
- Live on Nebraska
- Living Legacy Foundation of Maryland
- Mississippi Organ Recovery Agency
- Nevada Donor Network
- New England Donor Services
- New Mexico Donor Services
- OurLegacy
- Pacific Northwest Transplant Bank
- Sierra Donor Services
- Southwest Transplant Alliance
- Tennessee Donor Services
- Versiti Organ and Tissue Donation

UNOS brings collaborative improvement projects to the community

This DCD project is one of several collaborative improvement initiatives UNOS and the OPTN have undertaken in the past several years.

- A pediatric liver discovery project launched in 2020, and involved more than a dozen transplant hospitals.
- Past collaborative improvement projects include the Collaborative Improvement and Innovation Network, which aimed to reduce risk-avoidance behaviors and increase transplantation of deceased donor kidneys with a kidney donor profile indexgreater than 50 percent.
- A demonstration project is underway that focuses on effective practices regarding how donor hospitals refer potential deceased donors to OPOs.

For more information about collaborative improvement at UNOS, contact ci@unos.org.

*This article was updated on April 27, 2021.

UNOS

UNOS using a collaborative improvement model to increase DCD lung transplantation

Dec 14, 2022 | Collaborative improvement, Heart/lung, News

United Network for Organ Sharing has launched the Organ Procurement and Transplantation Network (OPTN) DCD Lung Transplant Collaborative, a national initiative to support efforts to increase the transplantation of donation after circulatory death (DCD) lungs by identifying and sharing effective practices.

More than 40 percent of the nation's adult lung transplant programs – 29 in total – are participating in the project. They will be guided by UNOS performance

improvement specialists in an "all teach, all share, all learn" environment that provides focused time, space and support for collaboration on improvement projects. The National Academies of Sciences, Engineering and Medicine (NASEM) have noted the success of UNOS collaboratives in the donation and transplant community and recommend a continued emphasis on sharing of effective practices.

Collaborative to address variation in practices, aims to increase organ transplantation

The volume of DCD lung transplants performed in the U.S. varies among programs, even while data indicates that DCD lungs can be transplanted with favorable outcomes[i], and while organ procurement organizations (OPOs) continue to recover DCD donors at increasing rates. The DCD Lung Transplant Collaborative seeks to address this variation in practice. This project will foster improvement efforts via a collaborative framework, and encourage organizational learning and community sharing to drive improvement.

The 29 participating hospitals are:

- Baylor University Medical Center (Dallas, Texas)
- Cedars-Sinai Medical Center (Los Angeles, Calif.)
- Cleveland Clinic (Cleveland, Ohio)
- Duke University Hospital (Durham, N.C.)
- Froedtert Memorial Lutheran Hospital (Milwaukee, Wis.)
- Hospital of the University of Pennsylvania (Philadelphia, Penn.)
- Inova Fairfax Hospital (Falls Church, Va.)
- Loyola University Medical Center (Maywood, Ill.)
- Medical University of South Carolina (Charleston, S.C.)
- Memorial Hermann Hospital, University of Texas at Houston (Houston, Texas)
- Mount Sinai Medical Center (New York, N.Y.)
- New York-Presbyterian Hospital/Columbia University Medical Center (New York, N.Y.)
- Newark Beth Israel Medical Center (Newark, N.J.)
- Luke's Health Baylor College of Medicine Medical Center (Houston, Texas)
- Joseph's Hospital and Medical Center (Phoenix, Ariz.)
- Stanford Health Care (Stanford, Calif.)
- Tampa General Hospital (Tampa, Fla.)

- The Ohio State University Medical Center (Columbus, Ohio)
- UC San Diego Health (San Diego, Calif.)
- UF Health Shands Hospital (Gainesville, Fla.)
- University Health Transplant Institute (San Antonio, Texas)
- University Hospitals of Cleveland (Cleveland, Ohio)
- University of California at Los Angeles Medical Center (Los Angeles, Calif.)
- University of California San Francisco Medical Center (San Francisco, Calif.)
- University of Kentucky Medical Center (Lexington, Ky.)
- University of Minnesota Medical Center (Minneapolis, Minn.)
- University of Nebraska Medical Center/Nebraska Medicine (Omaha, Neb.)
- University of Pittsburgh Medical Center (Pittsburgh, Penn.)
- University of Utah Medical Center (Salt Lake City, Utah)

The collaborative kicked off eight months of active participant engagement in December 2022. During successive four-month periods, participants will focus their performance improvement efforts on internal and external change concepts involving optimizing internal transplant processes and patient care practices and strengthening collaboration with OPOs. After the active engagement period concludes in July 2023, a project evaluation period will take place through September 2023.

UNOS brings collaborative improvement projects to the community

OPTN Collaborative Improvement projects focus on process and performance improvement rather than innovation, research, or policy development. While each project is designed with a different aim, they loosely follow the Model for Improvement developed by the Institute for Healthcare Improvement. Teams use a Plan-Do-Study-Act (PDSA) approach to identify areas of improvement, test interventions, track progress, and implement changes.

Learn more about Collaborative Improvement. For more information, email ci@unos.org

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[i] Levvey, B.J., Harkess, M., Hopkins, P., Chambers, D., Merry, C., Glanville, A.R. and Snell, G.I. (2012), Excellent Clinical Outcomes From a National Donation-After-Determination-of-Cardiac-Death Lung Transplant Collaborative. American Journal

The New York Times https://www.nytimes.com/2025/06/06/us/kentucky-organ-donations.html

Doctors Were Preparing to Remove Their Organs. Then They Woke Up.

A federal investigation found a Kentucky nonprofit pushed hospital workers toward surgery despite signs of revival in patients.

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By Brian M. Rosenthal

Published June 6, 2025 Updated July 20, 2025

Four years ago, an unconscious Kentucky man began to awaken as he was about to be removed from life support so his organs could be donated. Even though the man cried, pulled his legs to his chest and shook his head, officials still tried to move forward.

Now, a federal investigation has found that officials at the nonprofit in charge of coordinating organ donations in Kentucky ignored signs of growing alertness not only in that patient but also in dozens of other potential donors.

The investigation examined about 350 cases in Kentucky over the past four years in which plans to remove organs were ultimately canceled. It found that in 73 instances, officials should have considered stopping sooner because the patients had high or improving levels of consciousness.

Although the surgeries didn't happen, the investigation said multiple patients showed signs of pain or distress while being readied for the procedure.

Most of the patients eventually died, hours or days later. But some recovered enough to leave the hospital, according to an investigation by the federal Health Resources and Services Administration, whose findings were shared with The New York Times.

The investigation centered on an increasingly common practice called “donation after circulatory death.” Unlike most organ donors, who are brain-dead, patients in these cases have some brain function but are on life support and not expected to recover. Often, they are in a coma.

If family members agree to donation, employees of a nonprofit called an organ procurement organization begin testing the patient’s organs and lining up transplant surgeons and recipients. Every state has at least one procurement organization, and they often station staff in hospitals to help manage donations.

Typically, the patient is taken to an operating room where hospital workers withdraw life support and wait. The organs are considered viable for donation only if the patient dies within an hour or two. If that happens, the procurement organization’s team waits five more minutes and then begins removing organs. Strict rules are supposed to ensure that no retrieval begins before death or causes it.

The investigation criticized Kentucky Organ Donor Affiliates, which was coordinating donations in the state. Now called Network for Hope after a merger, it has said it always follows the rules and never removes organs until a hospital has declared a patient dead.

But the investigation found that the organization’s employees repeatedly pressured families to authorize donation, improperly took over cases from doctors and tried to push hospital staff to remove life support and allow for surgery even if there were indications of growing awareness in patients.

Some employees failed to recognize that hospital sedatives or illegal drugs could mask patients’ neurological condition, meaning they might be in better shape than they seemed.

In December 2022, a 50-year-old overdose victim began stirring less than an hour after being taken off life support and started looking around. The retrieval attempt was not immediately ended, nor was the patient given any explanation.

“The patient had no idea what was going on but was becoming more aware by the minute,” records noted.

After 40 more minutes — when the patient’s organs would no longer qualify for donation — the attempt was called off, and he was moved to an intensive care unit. He later sat up and spoke with his family before dying three days later, the investigation found.

The headquarters for Network for Hope, an organ donation organization, in Louisville, Ky. Luke Sharrett for The New York Times

Overall, the investigation flagged 103 cases as having “concerning features” and said problems were more likely to occur at rural hospitals. It noted more than half of transplants arranged by the Kentucky organization were from circulatory-death patients, above the national average.

Nationwide, officials recovered about 20,000 organs from this type of donor last year, nearly double the total in 2021, according to the Organ Procurement and Transplantation Network, which oversees the transplant system.

Federal regulators told the network last week that the Kentucky organization must increase training for staff and conduct neurological assessments on potential organ donors every 12 hours, among other changes.

On Thursday, the organization said it had received a report about the government investigation. “We will fully comply with all of their suggested recommendations,” it said in a statement.

The federal inquiry began last fall after a congressional committee heard testimony about the Kentucky man, Anthony Thomas Hoover II, who had an overdose in 2021. He was unresponsive for two days before his family agreed to donate his organs.

Over the next two days, the procurement organization moved toward surgery even as his neurological condition improved, the investigation found. During one exam, records show, he was “thrashing on the bed.” He was sedated to prevent further motion.

The hospital staff “was extremely uncomfortable with the amount of reflexes patient is exhibiting,” case notes read. “Hospital staff kept stating that this was euthanasia.” A procurement organization coordinator assured them it was not.

Donna Rhorer, Mr. Hoover's sister and legal guardian, with him after the canceled organ donation surgery. She said she hoped officials would adopt more safety standards.
via Donna Rhorer

When Mr. Hoover was taken for the retrieval, records show, he cried, pulled his knees to his chest and shook his head. A hospital doctor refused to withdraw life support. Mr. Hoover eventually recovered. Now 36, he has lingering neurological injuries.

In interviews with The Times, two former employees of the procurement organization said higher-ups tried to pressure the doctor to continue the retrieval attempt. "If it had not been for that physician, we absolutely 1,000 percent would have moved forward," said one of them, Natasha Miller, who was in the room. Three other former Kentucky employees said they had seen similar cases.

The investigation did not say if there was pressure on doctors who treated Mr. Hoover. Network for Hope did not respond to a request for comment on that case.

The Kentucky attorney general's office also launched an investigation into Mr. Hoover's case. On Thursday, the office said the review was ongoing.

0 words

Continue »

Brian M. Rosenthal is an investigative reporter who has worked at The Times since 2017.

A version of this article appears in print on , Section A, Page 15 of the New York edition with the headline: Set for Organ Removal, and Then They Woke Up

January 28th, 2025

My name is Danella Gallegos, and I am writing to you about my own near-death experience with the U.S. organ donation system.

My friend recently sent me a Tik Tok video of what happened to the man in Kentucky — TJ Hoover — when an organ procurement organization (OPO) attempted to recover his organs when he was not dead.

The same thing happened to me, and I am pleading with you to hold those responsible accountable to ensure that they are not able to harm others any longer.

The events below are corroborated by my sisters, Marlene Gallegos and Michelle Gallegos, and relay information and dates to the best of our recollection. We are all happy to talk with you if that helps your investigations in any way, and to share as much information as possible to the best of our recollections. Our goal is to protect patients in New Mexico and across the country by holding OPOs accountable, including removing OPOs who are dangerous and replacing them with those who have proven themselves to serve patients and their families with safety and integrity.

On September 2nd, 2022, I woke up and was hurting badly. I'd been dealing with many health issues, including cirrhosis of the liver and heart problems, and an ambulance took me to Presbyterian Hospital in Albuquerque, where I went into a coma.

My mother, Nadine Nieto, was told that there was no chance that I was going to make it — that there was no chance that I would survive. Someone from New Mexico Donor Services told my mother that I was a registered organ donor, and that my kidneys were healthy, and matched someone who needed them. My mother did not want to suspend my care, but she agreed based on what she was told, especially since she was told it was going to happen anyway.

On September 14th, 2022, my mother went to the hospital, and was told that the organ recovery was going to happen that day. A staffer from New Mexico Donor Services gave my sister Michelle a turquoise heart.

This is from my sister Marlene relaying her attempts to communicate with me:

> *"When we got to the hospital, we needed our mother to get Danella's purse and belongings because she was the power of attorney. As soon as we got the purse, staff started talking to us — I don't know if they were from the hospital or the OPO — and wanted to know if Danella's ID said that she was an organ donor, which it did.*
>
> *"Almost immediately after staff found out that she was an organ donor, they said that they had two people that would benefit from Danella's kidneys, and they had a match.*
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> *"I went to talk to the doctor that was on duty and asked if it's true that my sister was brain dead, and the doctor said: 'unfortunately, yes, it's true, Danella's brain dead, and will not have a chance to survive.' To the best of my recollection, they used the term 'brain dead' — but what I know for sure is that they said there was no chance that Danella would survive."*

I remember when I was in the hospital looking down and seeing a DNR tag on my leg. That was scary, because I never said that I did not want to be resuscitated.

The following is from my sister Marlene. I remember many of these events, including when she brought my daughter, Delicia, in to see me. Below are Marlene's recollections which happened in the couple of days before and including September 14th, 2022:

"I remember thinking: 'Oh my god! My sister is still alive.'

"But I was in the room alone with her, and when I'd told people before that I thought Danella was still alive, they were dismissing me like I was crazy, or that I was just grieving.

"So I went to my niece, Delicia, who is Danella's daughter, and told her: 'nobody believes me, but your mom is still alive. I don't know if she'll make it, so I want you to be able to say bye to her just in case. She is responsive to me, and everybody's saying I'm crazy, but I think that she will talk to you if you go with me. And I think she might wake up and have a different mindset, and maybe it might help her to see you.'

"I remember telling Delicia: 'I totally understand if you don't want to go, but if you do, I really feel like you might be a person like could save your mom's life. But you don't have to do this, and I would understand if you don't want to.'

"Delicia said: 'yes, I want to go.'"

"Delicia was crying and then she hugged me and said 'thank you for telling me the truth. How bad is she?' And I said 'you're going to probably freak out when you see her because she's just laying there very still. But I have a feeling that she'll respond to you because she's been responding to me.'

"So we walked into the room and I wet a paper towel and put it on Danella's head, and said 'Hi, Danella, it's your sister.' I would always tell her it's me, and later she told me that she was very scared the whole time because she would hear people saying, 'oh, we could take out her kidneys', and other conversations like that. She felt like everyone was tricking her, but she was very traumatized and trying to force herself asleep to just block out the trauma.

"So this time I had said, 'Hi, Danella, it's your sister Marlene, and guess who I have with me? I have your beautiful daughter, Delicia.'

"And then Danella's eyes just went, bam!, open all the way wide. She looked up at me, but not moving her head – just her eyes rolled up looking at me. And then both eyes just started watering. And then she picked up her head, barely, barely. It was shaky. And she turned her head to the left and started moving her mouth, trying to talk.

"I said, 'no, no, no, you can't talk because we have everything down your throat'. And then she gave me a thumbs up, and Delicia just started crying, and then Danella started crying. I told Danella: 'your kids love you, they miss you, and I need you still, Danella.'

"And then she shook her head 'yes,' and then lifted her hand up a little bit and looked at me as if to say 'can you unstrap my hand?" (Her hand had been strapped down.) So I said: 'yes, I can unstrap it, but you have to promise me you're not going to move your tubes because they're going down the throat and I don't know what it is connected to."

"And then Danella gave me another thumbs up. And so then I untied her hand and she lifted it up to Delicia and gave her the sign language sign for 'I love you.'

“That’s when Delicia sort of fell apart. She started crying and she was like, ‘I love you too, mom.’ And then I told Danella, ‘I don't know how strong your medicine is; I don't want you to forget and pull your tubes out, so I'm going to have to put the strap back on your hand’, and then she started wagging her index finger back and forth to tell me ‘no’, and signaling for me to give her a pen like by mimicking writing with her hand.

“So I asked if she wanted a pen, and she gave a thumbs up. So I gave her a pen and she wrote the word ‘starving’.

“I asked ‘what are you saying? Are you saying that you’re starving?’, and she nodded her head yes. And I was like, oh my gosh, let me go ask them for some food. I went immediately to the nurses’ station, and I asked them, ‘can you tell me the last time my sister had anything to eat?’ And I want to say her eyes freaked out looking at the screen. She didn’t want to tell me, and just said ‘I have to look into that.’ And I said, ‘I used to work at Presbyterian. I was kitchen manager and chef, and I know that you can see that information immediately. Can you just please give me that information?’

“The nurse responded ‘I'm not sure exactly what happened. I'm going to have to talk to somebody.’ The nurse told me that Danella hadn’t eaten for many days. I don’t remember the exact number. I do think I showed her the box though.

“Tears were flowing down my face, and I talked to a doctor, and demanded a second opinion from a different neurologist. Staff said that the neurologist was booked for a ways out and I said, ‘okay, please schedule for the next available time slot.’

“I was in the room with my sister and my fiancé, and I remember a doctor came in and pinched Danella for about one second and then Danella woke up – her eyes opened, and she looked at the doctor and rolled her eyes, probably wondering why he was pinching her like that.

“The doctor said ‘she responded to the pinch.’ And he then told Danella that if she makes it out of her situation, she could come back to the hospital and pinch him back. Then the doctor said to me, ‘OK, she's definitely not brain dead.’

“Another time, I also remember seeing a DNR tag on Danella, and I could see Danella was looking at it with her eyes open wide. She tried to lift her foot, but I remember it being strapped down. I said ‘What is this? Do you want this?’ Danella shook her head no. I removed the tag.

“I could tell that Danella was still there — that she could hear me and was communicating with me. Once, I went into the room and I held her hand. I was so lost for words that I just pulled a chair and I sat next to her and started crying, and then started praying.

“I had a scapular in my pocket that I had been praying with, and I placed it over my sister's head and I went to the sink and I got two paper towels and I wet them completely, and I also got a dry paper towel.

“I went to my sister, and I squeezed the wet paper towels over her head. She squinted her face and I said, ‘don't worry sis, I'm not going to let the water drip onto your beautiful face.’ I used the dry towels to dry her face since her hair was now a little wet. I combed it up slightly and put a new hair tie in.

“I opened the blinds completely, letting the natural light in. I turned on all the lights. I pulled out a Vicks inhaler. I put the inhaler in each of my sister's nostrils telling her to take a deep breath. She did. And I kissed her forehead and said, ‘it's your time to shine, sis. I need you to wake up when the doctor

downstairs talks to you, okay? And then she opened her eyes and nodded her head, yes, and a tear fell from her eye. I wiped it. And I told her, 'I love you, too.'

"I remember that I saved the DNR tag and the tissue box that Danella wrote on. I'm trying to find it."

On September 14th, 2022, my family was told that my organ donation recovery had been scheduled for that day. My sister Michelle remembers being in the room with my Grandma Edwina — the family had been told there was nothing else they could do.

I was given an honor walk to the OR, accompanied by my sisters Michelle and Marlene, my nephew (Marlene's son), Rudolfo Anaya, and my parents. The rest of my family was waiting in the chapel.

At the start of the honor walk, a representative of New Mexico Donor Services told my sisters that I might move, and not to be afraid if that happened. (My sister Michelle believes the staffer's name is [redacted] — she has [redacted] phone number saved in her phone.)

Michelle said that they were told they could accompany me to the pre-op room, and they would take me off life support. They said that I had 90 minutes to pass, and that when I died, they would rush me to the next room to remove my kidneys.

Marlene said that staff handed them three small clear containers with a cork to give it to Danella's children and inside there was a paper printed and they said it was her last heartbeat.

Michelle said that they were waiting for the doctor to arrive to unplug me from life support.

I remember waking up in the operating room and seeing people in masks. I was still intubated, so I couldn't speak, and I didn't know where I was. I could hear my sisters saying "we love you", and I could see medical equipment nearby.

This is from my sister Michelle:

"Marlene and I were standing at the end of Danella's bed. We were wearing masks, and holding a banner that New Mexico Donor Services had put on Danella during the honor walk. I was holding more of the turquoise hearts — eight of them that I had requested so that I could give one to each of Danella's kids, and then to her nieces and nephews.

"Everything felt strange, but we were trusting the process and what people had told us.

"All of a sudden we saw a big swallow. I said, "did she just swallow?" Marlene said "yes! C'mon sis, we're right here with you." I remembered The staffer from New Mexico Donor Services had told us that there could be reflexes — but it still felt so strange.

"They said Danella's situated, and were waiting for the doctor to pull the plug and to start the count. I went on Danella's right side, Marlene on her left. I saw tears and said "oh my god, sis, you're crying, huh?" She was facing me a little bit. She had dry tears. I started taking out the eyelash from a corner of her eye. Her eyes were closed and nonresponsive.

"Marlene said, "c'mon sis, you have young kids!" Then Danella's head turned towards Marlene. I thought that was weird — I didn't know what was happening. I looked at the people in the room and said

'did her head move?' Someone told me that she could still move, that she was getting oxygen to her brain.

"I was holding these heart stones that the Chaplain gave us. I had 8 — I was planning to give them to all the kids, Danella's three children and her nieces and nephews. I was holding her hand with those, and it seemed like she was pulling her hand away. That's when I told the nurse again.

"Then I noticed that Danella was facing me, and I thought, this is not an accident. I pulled my mask off and said, 'we are right here. No one's mad at you, if you have to stay asleep and be our angel that's ok.'"

"Then Danella wrinkled her eyebrows. I thought 'this is crazy, she's listening to me.'

"I said 'look at Marlene.' Danella turned her head that way. Then she pulled her head back against the pillow and her eyes opened a little bit. I said 'those are the people who are helping you, sis.' Then Danella relaxed her head."

My sister Michelle saw me swallow. She saw me moving my head. She saw my tears. She told the staff in the room that I was alive. The staff said that they had told her this could happen – as in, what might appear to family to be signs of life – but that that did not mean that I actually had any chance to survive. Clearly, that was not correct.

I remember Michelle talking directly to me. I remember the staff in the room telling my sisters that these were just reflexes. And I remember the nurse coming up to me. He said, "Danella, can you squeeze my hand?" I squeezed his hand, and then he freaked out.

He asked me "Can you give me a thumbs up?" I did — I tried my hardest, and moved my thumb. He freaked. He said "Can you blink three times?" I did. Three blinks.

Then I heard "Oh my god!" This is from my sister Michelle:

"A doctor finally came in — I remember she was wearing scrubs that were different from other people. She told my family that there was a change of plans. Marlene said it was a miracle.

"I was so happy that Danella was alive. I remember when they brought her back to her room, Phil Collins was playing – the song "Against All Odds." And I said to the staffer in the room 'Can you believe it?' They asked me to leave so that they could change the sheets.

"No one ever explained to us what happened. I thought, 'oh my god – did they just want her kidneys? Why are they doing this?' You just feel so helpless, and no one will answer your questions, or take the time to help you."

I was in the hospital for several more weeks, then went home.

Suffice to say, I am alive. And while I always wanted to be an organ donor if that would help someone, I never imagined being in a situation that I was in — with my family being told I was not going to make it, and people trying to harvest my organs when I was still alive.

This is from my sister Marlene:

"My sister is still alive today. She would not be if we hadn't intervened and pushed. My heart breaks to think what would have happened to her if we had not stood up for her, as well as what has almost certainly happened to an untold number of other patients who were killed for their organs."

After hearing the story of what happened to Mr. Hoover, I knew I had to speak out. It's terrifying to know that what happened to me has happened to other people around the country. I made it out alive, though I can only imagine how many have not.

I know that people rely on the organ donation system for transplants. I want to believe in a safe system where strangers help each other. But this is not what I experienced. I am happy to speak with anyone who can help, and may be able to access some supporting documentation, especially with help from any authorities. My sisters and mother will also share their experiences if this can help other people. My sister, Michelle, has said she still wonders: 'were they discriminating against us? Did New Mexico Donor Services just want my kidneys?'

Please finally hold people accountable so that Americans have a safe organ donation system that treats all patients with care. Our lives depend on it.

Please reach out to us with any questions.

Yours sincerely,

Danella Gallegos
Albuquerque, NM

Michelle Gallegos
Albuquerque, NM

Marlene Gallegos
Albuquerque, NM

Democracy Dies in Darkness

EXCLUSIVE

Thousands of lives depend on a transplant network in need of 'vast restructuring'

White House's U.S. Digital Service found that the technology that matches donated organs to patients has failed repeatedly

Updated July 31, 2022 More than **2 years ago**

By Joseph Menn and Lenny Bernstein

The system for getting donated kidneys, livers and hearts to desperately ill patients relies on out-of-date technology that has crashed for hours at a time and has never been audited by federal officials for security weaknesses or other serious flaws, according to a confidential government review obtained by The Washington Post.

The mechanics of the entire transplant system must be overhauled, the review concluded, citing aged software, periodic system failures, mistakes in programming and overreliance on manual input of data.

In its review, completed 18 months ago, the White House's U.S. Digital Service recommended that the government "break up the current monopoly" that the United Network for Organ Sharing, the nonprofit agency that operates the transplant system, has held for 36 years. It pushed for separating the contract for technology that powers the network from UNOS's policy responsibilities, such as deciding how to weigh considerations for transplant eligibility.

About 106,000 people are on the waiting list for organs, the vast majority of them seeking kidneys, according to UNOS. An average of 22 people die each day waiting for organs. In 2021, 41,354 organs were transplanted, a record.

UNOS is overseen by the Health Resources and Services Administration (HRSA), but that agency has little authority to regulate transplant activity. Its attempts to reform the transplant system have been rejected by UNOS, the report found. Yet HRSA continues to pay UNOS about $6.5 million annually toward its annual operating costs of about $64 million, most of which comes from patient fees.

“In order to properly and equitably support the critical needs of these patients, the ecosystem needs to be vastly restructured,” a team of engineers from the Digital Service wrote in the Jan. 5, 2021, report for HRSA, which is part of the Department of Health and Human Services.

“There are little to no incentives for … UNOS … to ever modernize the operations of the [system] and improve the current processes or technology, and the government has very little leverage,” the investigators wrote.

UNOS considers its millions of lines of code to be a trade secret and has said the government would have to buy it outright for $55 million if it ever gave the contract to someone else, according to the report.

Transplant doctors have complained for years about archaic aspects of the technology for sharing data and getting organs to the right place as quickly as possible.

“When nearly 100 percent of hospitals use electronic records, the notion that we rely on human beings to enter data into databases is crazy. It should be 85 to 95 percent automatic,” said University of California at San Francisco surgery vice chair Ryutaro Hirose, a former chair of the UNOS liver transplant policy committee. “We could concentrate more on improving patient care.”

Hirose said he had been forced to turn to travel sites such as Expedia to make plans for transporting organs. “With DoorDash, I know where my food is. That should at least be the case for a lifesaving organ,” he said.

Carrie Frenette, who until December was medical director of liver transplants at Scripps Green Hospital in the La Jolla neighborhood of San Diego, echoed that complaint. “You have to have your coordinator at your center arrange transportation, and there is no help from UNOS,” Frenette said.

“We had a very sick woman in the ICU on life-support systems. We finally got an organ offered, but there were difficulties in getting the surgeons to her and getting the liver back, and a week later she died,” Frenette said.

In an interview, UNOS chief executive Brian Shepard said the nonprofit was improving tracking and had a travel-planning app in development.

Shepard said the Digital Service report “reads more like an op-ed” than a paper based on thorough research. He said the transplant system is secure and effective.

Yet leaders of the Senate Finance Committee, which has scheduled a hearing on the system for Wednesday, grew so alarmed during a closed-door briefing earlier this year that they warned officials at the Department of Homeland Security and intelligence agencies in a letter seen by The Post that they had “no confidence” in the security of the transplant network. They asked the White House to intervene to protect it from hackers.

“We request you take immediate steps to secure the national Organ Procurement and Transplantation Network system from cyber-attacks,” the committee chair, Sen. Ron Wyden (D-Ore.), and Sen. Charles E. Grassley (R-Iowa) wrote to Federal Chief Information Officer Clare Martorana in February.

The senators wrote that “no one working for the federal government has ever examined the security of this system” and the government “has not imposed any cybersecurity requirements on UNOS.” The Digital Service report also noted that government experts have never been allowed to inspect the computer code that runs the complex transplant system.

An official in the administration’s Office of Management and Budget, which oversees the Digital Service, said OMB has worked with Health and Human Services on steps to “ensure the cybersecurity” of the transplant system.

HRSA said it was still working with the Digital Service and other experts. “We are consulting with the United States Digital Service to modernize the Network’s IT and we have sought best insights from patients, academics, tech experts, and clinical leaders,” it wrote in a statement.

UNOS’s Shepard stressed that the Digital Service report was still in draft form. But a former White House official involved in the review, who spoke on the condition of anonymity because he was not authorized to discuss the Digital Service findings, said that the report is normal; such reports are routinely labeled as “pre-decision” drafts because they are prepared for cabinet secretaries and their deputies who must then choose to act.

That label also exempts the reports from Freedom of Information Act requests, and UNOS said it had been unable to obtain the document until The Post provided the text.

Shepard, who is stepping down in September, said his organization is audited yearly by HHS. He said that if officials visit the UNOS office, they can review specific chunks of the source code.

“The code is extremely large,” Shepard said. “They can come in and ask for specific pieces.”

UNOS said it was audited in 2020 by HRSA and last year by the office of the HHS inspector general, which is checking the security controls. A former HHS official familiar with the transplant system said the department ran through a checklist of questions but never won access to the system itself.

UNOS said in a statement that its refusal to turn over the full code is part of “an important balance: providing HRSA and other auditors the access they need to ensure the system’s security while limiting wider access in order to safeguard patient data and protect UNOS’ intellectual property.”

UNOS also said it would soon get a security penetration test by an HHS-recommended firm and a review of its “cyber-hygiene” by the U.S. Cybersecurity and Infrastructure Security Agency, the Department of Homeland Security division responsible for computer security.

UNOS oversees what is formally known as the Organ Procurement and Transplant Network, a complex collection of about 250 transplant-performing hospitals; 57 government-chartered nonprofits that collect organs in their regions; labs that test organs for compatibility and disease; and other auxiliary services.

Located in Richmond, UNOS sits at the center of the system. It is the only organization to ever hold the 36-year-old contract to run the operation, currently a multiyear pact worth more than $200 million, funded mainly by fees patients pay to be listed for transplants.

UNOS oversees controversial policies that determine which patients have priority for lifesaving kidneys, hearts, livers and other organs. It reviews mistakes by members of the network and maintains the waiting list for organs. And it runs the complex technology that connects the entire enterprise.

Part of UNOS's job is to monitor the performance of organ procurement organizations (OPOs) and hospitals where transplants are performed. When either is reported to have needlessly wasted an organ or endangered patient safety, UNOS is supposed to look into the incident. It can provide advice to the organization on how to improve or impose a variety of sanctions.

Critics have long said UNOS does little with many of these complaints, leaving the problems that caused them unresolved. Its findings and the work of its investigators are not made public.

Only the government, however, can revoke an OPO's license to operate. That has never happened in the history of the transplant system.

More than 20 percent of all kidneys procured for transplant in the United States are not used, according to data from the Scientific Registry of Transplant Recipients. That rate reached a new high in 2020, when 21.3 percent of procured kidneys were not transplanted, a registry report found. The reasons are in dispute, with members of the network often blaming each other.

European countries report much lower "discard rates" for kidneys, according to various studies. France had a kidney discard rate of 9.1 percent from 2004-2014, a 2019 study found. The United Kingdom has a rate ranging from 10 to 12 percent. Eurotransplant, a consortium of eight countries including Germany, reported a rate of about 8 percent.

Some of the 57 OPOs also fail to meet government standards for their main job — collecting organs. After decades of allowing them to calculate and report their own compliance data, the government in 2019 took steps to hold the worst of them accountable.

As for UNOS itself, a comprehensive study requested by Congress was conducted by the National Academies of Sciences, Engineering and Medicine. In February, it came to one of the same conclusions as the Digital Service, recommending splitting the information technology infrastructure into a separate contract or requiring modernization when UNOS's current contract comes up for rebidding, likely in 2023.

“HHS should ensure that the OPTN uses a state-of-the-art information technology infrastructure that optimizes the use of new and evolving technologies to support the needs and future directions of the organ transplantation system,” the Academies wrote, adding that the system “could save additional lives” if it acted more cohesively with better oversight.

The Digital Service investigators found that the critical computers connecting the transplant network have crashed for a total of 17 days since 1999, with one February 2021 outage lasting about three hours, according to follow-up work conducted by the investigators. That’s a critical problem when organs can lose vitality after as little as four hours. Shepard blamed a firewall failure for the three-hour crash, adding that there have been no unplanned disruptions since then.

In another case, the former official in the Department of Health and Human Services said, UNOS allowed a programming error to push some lung patients lower on the priority list than they should have been. The mistake was eventually caught by a different federal contractor analyzing patient data, he said.

UNOS officials said they had gone back to assess the impact of the mistake and found that it had delayed some matches but that all the patients had eventually gotten one.

As portrayed in the report and interviews with current and former government officials, the technology that runs the transplant system is not only far behind current standards but also unlikely to catch up. That’s because UNOS owns the system under an unusual contract with the Department of Health and Human Services that prevents meaningful oversight.

The 1984 National Organ Transplant Act established the transplant network as a “quasi-governmental agency” — with UNOS in mind — run by a nonprofit under a single contract, the Digital Service report said.

That “leaves the government with only a monitoring function to make sure the OPTN contractor follows the statute, rather than the kind of oversight authority” found in more traditional relationships between government and contractors, the report said. Any change in the way the system operates likely would require Congress to amend the 1984 law.

In its statement to The Post, HRSA said it was “committed to using all available tools to modernize the Organ Procurement and Transplantation Network, including leveraging the upcoming contracting process to increase accountability.” It also said it would “welcome the opportunity to work with Congress to update the nearly 40-year-old National Organ Transplant Act.”

UNOS has touted ambitious efforts to upgrade its technology, but most were quietly abandoned when they ran into problems, the report said.

UNOS's shortcomings are compounded by HRSA's own failings. The agency lacks technical expertise, can't force the network to turn over data, and is so concerned about upsetting the nonprofit that it has been reluctant to push for more intensive demonstrations of the system, according to the report and interviews. That allows UNOS "to wiggle through and around most new contract requirements for the [transplant network's] technology by hand-waving at change with technical jargon, while making no substantive progress," the Digital Service report said.

"There are no requirements, or mechanisms to create requirements, in the current contract" that would force UNOS to upgrade its technology, the report said. "UNOS knows this, and it is why when asked directly about their timeline for modernization, they point at HRSA and just say, 'We'll do it when they tell us to.' "

UNOS has not allowed anyone in government to analyze its code base, instead providing only the English-language description of it, known as pseudocode, officials said. That surprised Digital Service analysts; it was the only time that its engineers' request to inspect code used by government agencies and contractors has been refused on nearly 100 occasions, according to the former White House adviser who was involved but not authorized to speak.

UNOS also "has at times even threatened to walk away and continue operating the [transplant network] without a contract, despite the fact that it would be illegal for them to operate such a network independent of a government contract," the Digital Service wrote. That has kept HRSA "hesitant about pursuing avenues for real change in this program," it added.

UNOS said that claim twisted a conversation during contract talks years ago in which it tried to assure the government that it would keep operating even if the old deal expired, rather than harm patients. But the former HHS official said the department saw the statement as a hardball tactic to put pressure on the government to meet UNOS's terms.

Among the key technical findings of the report was that the vast majority of UNOS's operation was running on a local data center instead of on the kind of cloud computing systems that have become the norm for most large businesses and public agencies. Switching to a cloud computing system would reduce system lags and downtime, allow greater automated access, and add computing power to support machine learning, the Digital Service said.

UNOS said that it used both public and private cloud architecture, with the latter in two physical locations.

The report found that the system still requires manual data entry that can lead to mistakes or narrow the timing window for successful organ matches.

Shepard said that in some cases hospitals had not modernized enough to automate data entry.

The Digital Service report also said the organizational structure of the software that matches donors with patients is so clunky that even a single change in priority policy can take a full year to be reflected in the code. Shepard acknowledged that some shifts take that long.

The Digital Service team also accused UNOS of misplaced priorities in its approach to technology.

"They have placed on their product roadmap things like artificial intelligence, mobile delivery of functionality and advanced predictive modeling," the team wrote. "Where UNOS should be focused on getting the basics right for the core functionality before they layer in additional complexity … they instead seem intent on adding shiny technology and distracting program stakeholders."

Several former officials familiar with the transplant system confirmed the Digital Service's description of UNOS's resistance to government oversight. Robert P. Charrow, the HHS general counsel during the Trump administration, called the situation "the most topsy-turvy relationship I've ever seen."

In its report, the Digital Service said it identified three other unspecified organizations with "clear capabilities" to take over UNOS's technology.

But potential competitors for the contract are waiting to see how HRSA writes the requirements in a new bidding document. The last time the contract was up, in 2018, potential applicants ultimately were dissuaded by requirements that HRSA included that called for bidders to have at least three years of experience managing transplant projects of similar complexity — a description that fits only UNOS or a group running a transplant system in another country.

When the new request for proposals will be issued is uncertain. The government has so far issued only a "request for information," a step before it calls for bids. That document describes a $248 million deal (presumably over multiple years), with $27.7 million coming from the government and the rest from fees patients pay to be listed for transplants.

Any transition to another vendor would cost more than $71 million, the Digital Service report estimated, including $55 million to purchase the current systems. The Digital Service called the figure "exorbitant" and said "the government should never have to be in a position to make the purchase of the existing systems" in order to modernize technology.

Even so, said the former White House adviser involved in the review, the government could recoup that much in a single year by improving the technology involved.

And for the same expenditure as now, according to the former HHS official not authorized to discuss the contract publicly, "You would be hard pressed to think you couldn't at least get 5 percent better, which would be thousands of transplants."

Todd C. Frankel contributed to this report.

What readers are saying

The comments on the article express significant criticism of UNOS, the organization responsible for managing organ transplants in the U.S. Many commenters argue that UNOS's outdated technology and monopolistic practices contribute to inefficiencies and preventable deaths. There... Show more

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