HRSA
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Health Systems Bureau/Division of Transplantation
5600 Fishers Lane
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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]

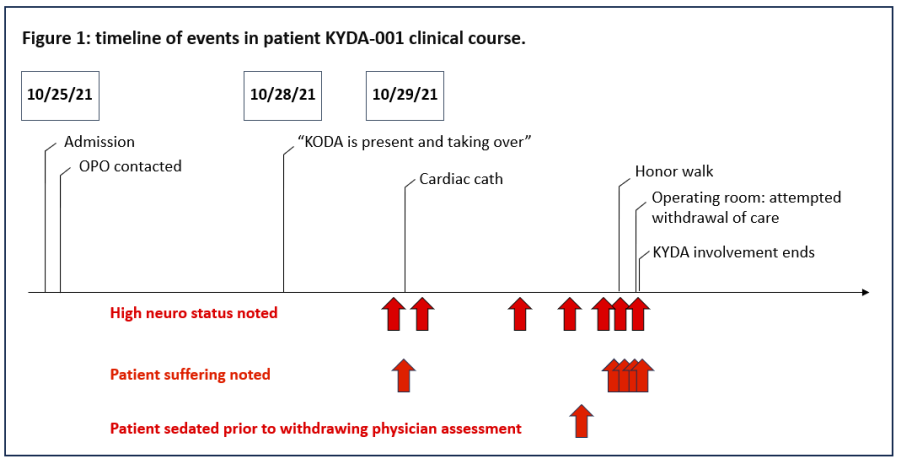
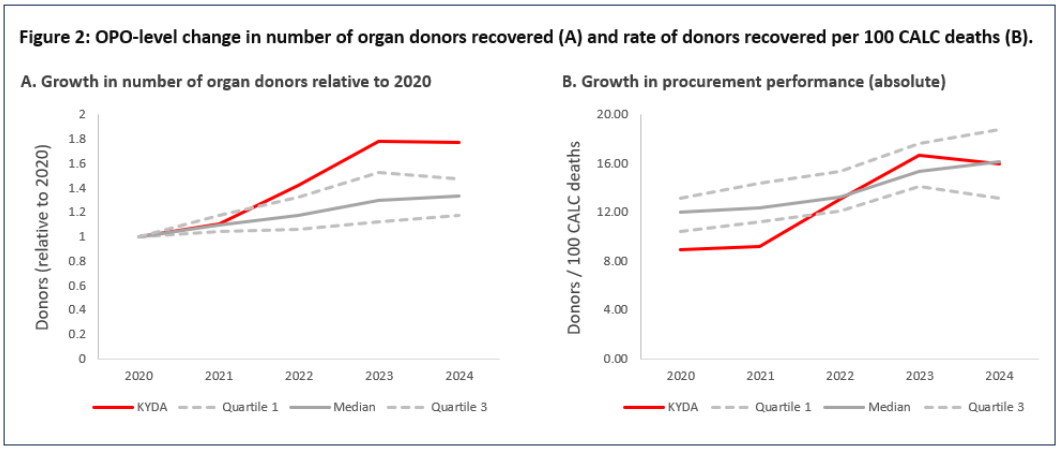


Figure 1 displays a simplified timeline of events in patient KYDA-001's care. KYDA staff documented improving neurologic status and concerns from physicians and nurses, but there is no evidence of deliberative process to reassess the likelihood that this would be a successful organ recovery. Instead, 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]

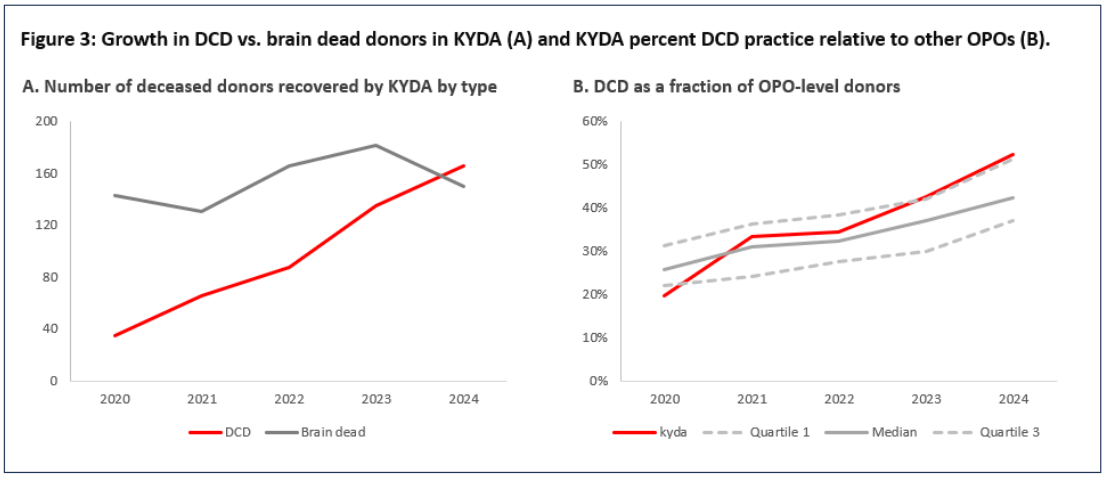
BACKGROUND ON ORGAN PROCUREMENT BY KYDA

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]

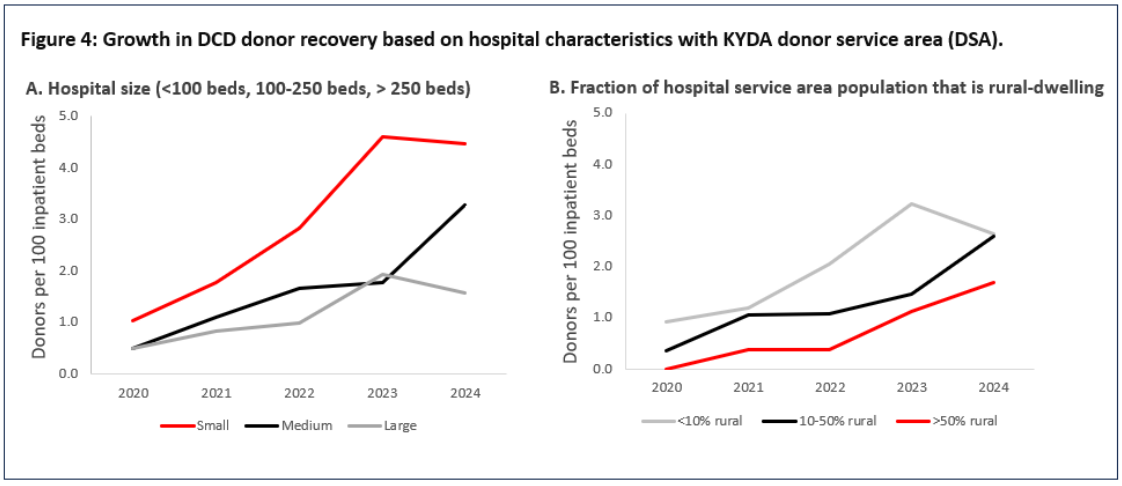


The gain in organ donors recovered by KYDA came almost entirely from increases in DCD. As shown in **Figure 3A**, the number of brain dead donors recovered by KYDA has been stagnant since 2020, while DCD donors rose from 35 in that year to 163 in 2024. As shown in **Figure 3B**, KYDA's shift to majority-DCD 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

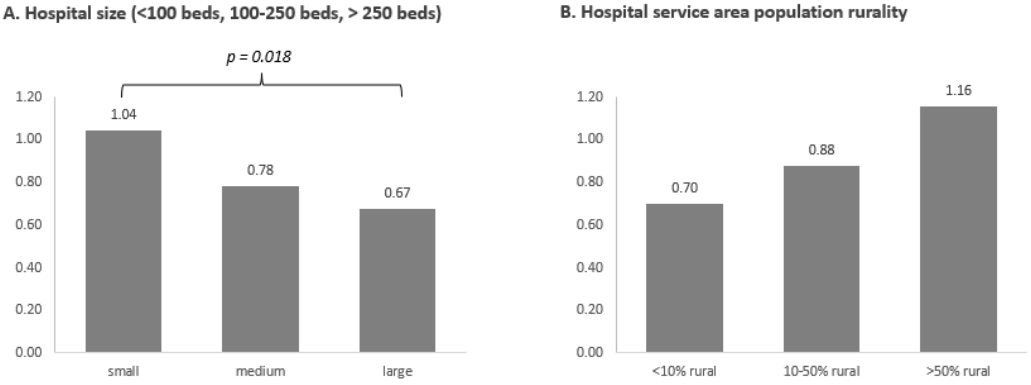
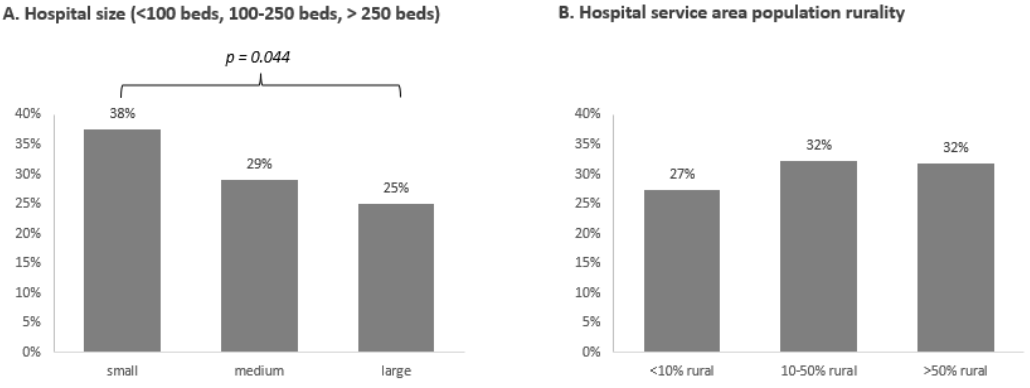


Figure 6: Fraction of ANR cases with concerning features by hospital characteristic with KYDA DSA, 2021-2024



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*."

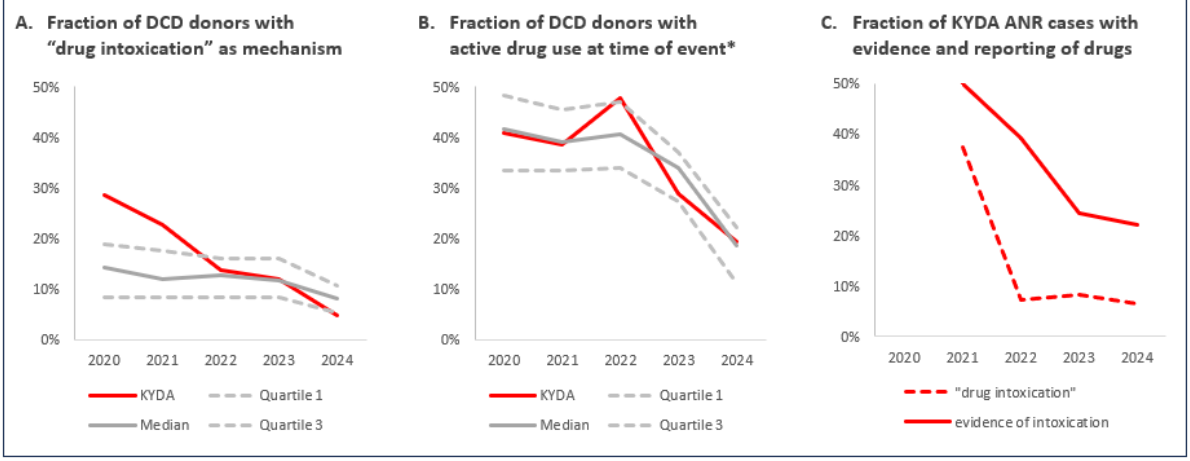
No further documentation on the nature of the complaint or its response was provided.

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.*



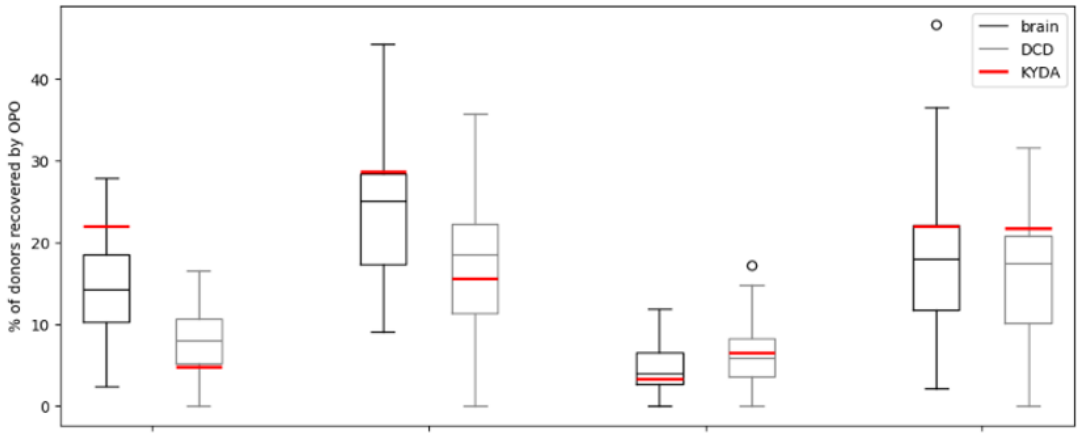
Variable and misleading reporting of drug overdose as donors' mechanism of death in OPTN data has previously been documented.[35] The physiologic effects of these drugs can include death through cardiovascular collapse, asphyxiation, anoxia, or event traumatic injury in the event of intoxication. As 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.