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The MTN Minute

A review of the legislation and policies impacting organ, eye and tissue donation

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A Message From the Editor

Dear readers,

We at Midwest Transplant Network (MTN) have had a very productive second half of the year, especially following the opening of our Donor Care and Surgical Recovery Unit (DCU). Since its opening on Sept. 5, MTN has transferred approximately 35 eligible donors from hospitals in Kansas and Missouri to the newly built DCU, yielding 110 organs for transplant. MTN's clinical staff members have achieved impressive outcomes in the DCU, including a seven-organ donor, a 67-year-old lung donor, and the successful rehabilitation, recovery and transplantation of a donor's heart that was initially deemed unlikely to be suitable for transplant at the hospital. As anticipated, MTN is seeing an increase in the number of transplantable organs while reducing the strain on local hospitals by freeing up hospital beds, staff members and operating rooms for living patients.

Additionally, we have been consistent with our lobbying efforts in conjunction with the Association for Organ Procurement Organizations (AOPO), meeting with legislators during Advocacy Day on Sept. 15. My meetings with legislators focused on the removal of language from Section 371(b)(3) of the Public Health Service Act that remains a disincentive for some transplant centers to transfer donors to MTN's DCU, unnecessarily complicating the organ transplantation process.



Salama Gallimore (left), speaks with former Sen. Roy Blunt, R-Mo., (right) during a September meeting scheduled in support of AOPO's Advocacy Day.



Salama Gallimore (left), poses with Legislative Assistant Christiana Reasor, of Sen. Jerry Moran's (R-Kan.) office, following an advocacy meeting on Sept. 15, 2022.

MTN President/Chief Executive Officer Jan Finn, RN, MSN, and other organ procurement organization (OPO) CEOs have also been in contact with leaders at the Health Resources and Services Administration (HRSA) to discuss the problematic language in the Public Health Service Act, Medicare cost reporting procedures that disincentivize transplantation and general improvements to the U.S. transplantation system.

Additionally, in November, Finn, Vice President & Chief Clinical Officer Lori Markham, MSN, RN, CCRN-K, CPTC, and I were able to attend an AOPO Director's meeting in Dallas. We discussed and implemented recommendations from National Academy of Sciences, Engineering and Medicine's (NASEM's) Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution, with a focus on data-sharing; diversity, equity and inclusion; and legislative advocacy to assist the OPO community in doing its part to reach [50,000 annual organ transplants from deceased donors by 2026](#).

Consensual Donation and Research Integrity Act of 2022 — Senate Bill 4929

The process for donating a body part for the purpose of transplantation is highly regulated by multiple federal agencies; however, the same process does not exist to govern the donation of a body or body parts for research. Therefore, U.S. Sens. Chris Murphy (D-Conn.) and Thom Tillis (R-N.C.) introduced the [Consensual Donation and Research Integrity Act](#) in September to protect the dignity of individuals who donate their bodies to education or research. If passed, the Act would create standards for registration, inspection, chain of custody, packaging and tracking of donated bodies to ensure they arrive at the intended legitimate research or educational institution. OPOs and other members of the Organ Procurement and Transplantation Network (OPTN) are excluded from registration and other requirements of the bill. However, MTN regularly works with families of donors who have elected to donate their body or body parts to research or education programs and transfers donors in accordance with the donor's or donor family's wishes and verified, signed authorizations.

MTN may have additional administrative and recordkeeping duties related to the bill, if passed, including the production of certain documents and authorizations to registered entities. This bill was introduced on Sept. 22, 2022, to the U.S. Senate, and no actions have occurred related to the bill following its introduction.

UNOS Names New Interim CEO

The United Network for Organ Sharing (UNOS) announced Maureen McBride, PhD, as its new Interim Chief Executive Officer following [Brian Shepard's retirement](#) on Oct. 1, 2022. McBride has served UNOS in a variety of leadership roles since 1995, most recently as Chief Operating Officer. The UNOS Board has begun a national search for a permanent CEO. Shepard's resignation was preceded by the release of previously sealed emails used as evidence by a federal court in a [lawsuit](#) filed by a group of plaintiffs, including transplant centers in Kansas and Missouri, that believed new liver allocation rules would reduce their access to lifesaving transplants by transferring more organs to medical centers in larger

cities where the demand for these organs is greater. In these emails, Shepard made [disparaging remarks](#) about those in support of the previous system, which allocated organs based on a more restrictive geographic distance from the donor.

MTN welcomes CEO McBride and other new UNOS administrators and looks forward to continuing joint efforts to improve and refine the U.S. transplantation system.

Revisions to the Uniform Death Declaration Act

The [Uniform Determination of Death Act](#) (UDDA) is a piece of model legislation, or non-binding legislative text, used to serve as a guide for state lawmakers that has been adopted nationwide to provide a more concrete definition of death for legal purposes. The American Medical Association and the American Bar Association have approved the current version of the UDDA. The UDDA Drafting Commission is composed of commissioners — private individuals with relevant expertise who volunteer to work for specific committees affiliated with the National Conference of Commissioners on Uniform State Laws. In advance of the UDDA Drafting Committee's December meeting, MTN's Jan Finn and Salama Gallimore met with David English, Esq., the Commissioner representing Missouri, to learn more about the Committee's work. MTN is also in regular contact with Christina Strong, Esq., who is acting as an Observer representing the interests of OPOs to the Drafting Committee.

While OPOs like MTN do not declare brain death, OPOs verify that a physician has declared a potential donor's death pursuant to protocols and state law; they also receive notification of every death and imminent death, regardless of how that death is determined, whether by neurologic or circulatory criteria. Additionally, OPO staff remain available for the families of donors before, during and after the death, providing support. For these reasons, MTN has proactively engaged with Commissioners to support any change that would further legal clarity based on broadly held medical standards to further public trust in the brain death declaration process and eliminate legal confusion.

One of the proposed changes to the UDDA relates to the how death is defined. Currently, the UDDA offers two definitions describing when an individual may be declared legally dead:

1. Irreversible cessation of circulatory and respiratory functions, or
2. Irreversible cessation of all functions of the entire brain, including the brain stem.

There is consensus that the current UDDA is not perfectly reflective of current medical standards, which would support the use of the term "permanent" instead of irreversible as well as the deletion of the phrase "entire brain, including the brain stem," as this may require the hypothalamus to be included, a circumstance that is not currently supported by medicine.

The Drafting Committee is also evaluating changes to the UDDA related to brain death testing, including a proposal to legally require notice of a neurological exam to a patient's legal next of kin. While notice of a brain death exam is a best practice, critics of the imposition of a notice requirement view this inclusion as both outside the scope of the UDDA and as an incursion into physicians' scope of medical practice.

Additionally, the Drafting Committee has contemplated revisions to the UDDA that would require a patient's legal next of kin to consent to a brain death exam and permit the next of kin to opt out of brain death testing. OPOs are generally not supportive of these revisions

because the changes effectively provide legal next of kin the ability to block the neurologic death determination exam or death declaration, which may result in a lack of medical information and grave harm to the patient; invite increased uncertainty at the end of life; and may threaten an individual's irrevocable gift of life through organ donation. At least three states (New Jersey, California and Illinois) allow some restriction on declaration of death determined neurologically, and in those states, reasonable accommodations are based on the *patient's* — not the family's — belief system.^[1]

MTN will continue monitoring the Committee's revisions and work with AOPO to engage in advocacy that is supportive of patient safety and respectful of an individual's right to make an anatomical gift after death.

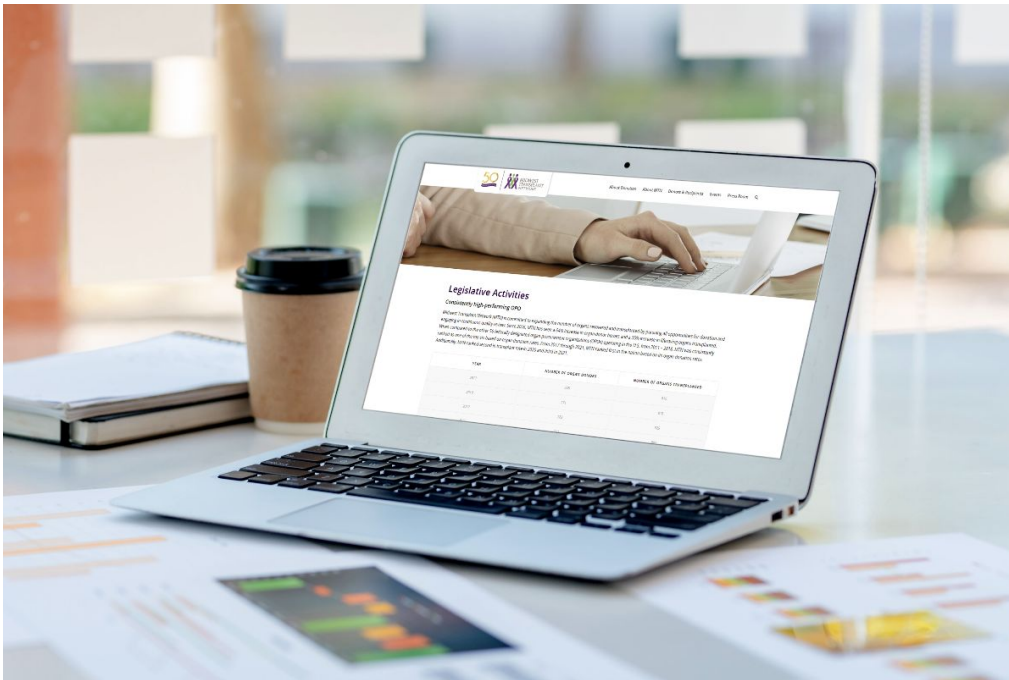
[1] Biel S, Durrant J. Controversies in Brain Death Declaration: Legal and Ethical Implications in the ICU. *Curr Treat Options Neurol.* 2020;22(4):12. doi: 10.1007/s11940-020-0618-6. Epub 2020 Mar 18. PMID: PMC7223748.

Revisions to the Uniform Health Care Decisions Act

AOPO is also monitoring proposed revisions to the Uniform Health-Care Decisions Act (UHCDA) by the UHCDA Drafting Committee, and Christina Strong serves as an Observer representing OPOs' interests to the Committee. The UHCDA consolidates various state laws regarding adult healthcare and healthcare powers of attorney and aims to assist individuals and medical professionals to assure an individual's right to choose or reject a particular course of treatment. The UHCDA also provides forms for executing a healthcare power of attorney, providing written instructions to a healthcare provider and authorizing anatomical gifts. OPO concerns center on the proposed form for an advance directive, which includes an anatomical gifting section (Part 3). This section of the form permits an individual to authorize an anatomical gift and designate the gift for specific purposes — for example, transplant, education and research. However, as written, it is possible for a person to determine that the language in Part 3 conflicts with other desires set forth in the document.

For example, an individual may indicate, as provided in Part 2, Instructions for Health Care, that healthcare providers are “not to prolong life” if he/she/they are suffering from an incurable disease or irreversible condition, and this election could be read to conflict with the need for medical staff to administer procedures necessary to evaluate, maintain, or preserve organs or tissues. Therefore, AOPO is seizing the opportunity to encourage the UHCDA Drafting Committee to add the following clarifying language to the end of Part 2 of the UHCDA to address the potential conflict: “Notwithstanding any directive contained in any other section of this document, I direct (or consent to) the commencement and maintenance of any medical procedure necessary to evaluate, maintain or preserve my organs or tissues for purposes of donation for transplant, including, but not limited to, mechanical respiration.”

The OPO community is pleased with the progress of the Committee in revising the UHCDA and the Committee's willingness to hear commonsense proposals from relevant stakeholders.



A New Webpage!

MTN has developed a new webpage where you will find legislative updates; relevant articles; access to past volumes of the MTN Minute; a historical database of MTN's comments submitted to the Federal Register; copies of letters sent to legislators and federal administrators; and information regarding MTN's stakeholders and partners.

Please check out the new page [here](#). As MTN continues to evolve, we hope to continue adding content to this page.

If you have suggestions for additional content on the webpage, please do not hesitate to contact Salama Gallimore at sgallimore@mwn.org.

In the News

On Nov. 11, CBS Mornings aired a [five-minute segment](#) to its national audience rehashing serious accusations, some of which are inaccurate, that OPOs are failing. CBS reporter Anna Werner interviewed the Chief Executive Officer of an Ohio OPO as well as Rep. Raja Krishnamoorthi (D-Ill.).

Werner focuses on data quality and the investigation into OPO performance launched by the House Oversight Committee in December 2020. Despite the story's criticism of OPOs, CBS did use an AOPO statement that "in the last five years, OPOs have increased the number of deceased organ donors by 35%." In response to the story, AOPO President Barry Massa sent a [letter](#) to Werner, providing more background information and context about the state of the organ donation and transplantation system. Specifically, the letter employs language from the NASEM report to inform Werner:

...the entire system — CMS, UNOS, transplant centers, OPOs and donor hospitals — bears responsibility for increasing the number of transplants in the U.S. However, you did not reference this seminal report in your story, despite having it at your

fingertips. NASEM found that, “on average, patients who die waiting for a kidney had offers for 16 kidneys that were ultimately transplanted into other patients, indicating that many transplant centers refuse viable kidney offers on behalf of those on the waiting list (Husain et al., 2019).

Additionally, according to the report:

The rate at which kidneys go unused in the United States is much higher than other developed countries (Mohan et al., 2018; Stewart et al., 2017). For example, the U.S. rate of nonuse for procured organs is nearly double the rate in France (Aubert et al., 2019). Approximately 62% of kidneys not used in the United States would likely have been successfully transplanted in France (Aubert et al., 2019).

Importantly, the letter also speaks to the impact of negative news stories on donor registrations. In closing the letter, Massa offers to brief Werner further on these topics and be a source for future stories.

Feel free to review these additional news stories^[2]

- [Chairman Krishnamoorthi, Rep. Porter Raise Concerns About Data Collection and Management at Organ Procurement Organizations](#)
- [National Kidney Foundation: Kidney Patients Deserve a High-Performing Organ Transplant System](#)
- [How Organ and Tissue Donation Companies Worked Their Way into the County Morgue](#)
- [Bias Against Older Organ Donors May Be Leading to Smaller Organ Supply for Transplants](#)
- [AdventHealth Criticizes Organ Transplant System](#)
- [‘Brain Death’ Marks the True End to a Person’s Life](#)
- [Organ Transplants Are Up, but the Agency in Charge Is Under Fire](#)
- [Organ Transplant Milestone: As U.S. Crosses 1 Million Mark, Advances Offer Hope for Millions More](#)
- [U.S. Reaches Historic Milestone of 1 Million Organ Transplants](#)
- [From Recovery to Reception: Kidney Transplant Collaborative Grant Funds Innovative Program to Increase Transplant Rates Nationwide](#)

^[2] MTN does not espouse or support the views expressed in these linked articles, nor has the Editor reviewed all articles for accuracy; rather, these articles constitute a sampling of recent press relevant to this volume of the MTN Minute or mentioning OPOs, additional stakeholders of the U.S. transplantation system, and the laws and regulations that govern them.



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