



The MTN Minute

Vol. 2, No. 1
February 2020

THE IMPACT OF ORGAN & TISSUE DONORS from the MTN Service Area in 2019*



• ALL POSSIBLE WITH THE HELP OF OUR PARTNERS •



* Based on MTN data as of Jan. 16, 2020. Data subject to change based on future data submission or correction.

A Message from the Editor

Happy New Year, and welcome to the second volume of The MTN Minute! In 2019, MTN engaged in legislative action at the state and federal levels, hosted a U.S. Congressman and held an event to connect with government affairs professionals and attorneys from hospitals in the KC metro. MTN also engaged in the policymaking process by formally submitting comments to the Federal Register and the Secretary of Health and Human Services to advocate for a standardized, reliable OPO performance metric and to



comment on proposed revisions to the U.S. Public Health Service guidelines for donor and recipient infectious disease testing. Currently, MTN is busy working through the new Centers for Medicare and Medicaid Services-proposed OPO performance metrics, and we are happy to report that using performance modeling under these new metrics, MTN consistently ranks as one of the top five performing OPOs in the country! MTN's Tissue Services, Organ Services and Laboratory departments each had a record-setting year working with our partners to save and enhance lives through organ, eye and tissue donation.

With the 2020 legislative session in full swing in Kansas and Missouri, I have been busy monitoring proposed legislation that may impact MTN's mission. Chief Executive Officer Jan Finn, RN, MSN, and I are working to establish new relationships with legislators and keep communication lines open with lawmakers who support organ, eye and tissue donation, with upcoming trips planned to Jefferson City, Missouri; Topeka, Kansas; and Washington, D.C. I hope you enjoy the articles in this volume of "The MTN Minute" as much as I enjoyed writing them.

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Fall Visit to D.C. Lawmakers

Finn and Gallimore made a special trip to Washington in October to speak to lawmakers about OPO performance and proposed performance metrics. They attended in-person meetings with legislative staff members who serve Representative Roger Marshall, MD (R-KS) and Senators Jerry Moran (R-KS) and Roy Blunt (R-MO) to continue conversations regarding OPO performance indicators and proposed performance metrics. They also discussed policies pertaining to the broader sharing of organs and language in the Labor, Health and Human Services Committee appropriations bill that expressed support of the proposed allocation policy currently under litigation. Gallimore also met with Senator Pat Roberts' (R-KS) staffers for the first time and connected with Representatives Sharice Davids' (D-KS) and Emanuel Cleaver's (D-MO) healthcare policy advisors.

Public Comment Round Up

MTN leaders had exciting opportunities to submit comments on a proposed policy and a proposed regulation revision:

Proposed Revisions to the 2013 Public Health Services (PHS) Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) through Organ Transplantation

Together, Dr. Taba Kheradmand, Finn and Gallimore drafted comments in response to proposed revisions to the 2013 PHS Guideline. MTN supports efforts to reduce the risk of disease transmission while saving lives through organ donation and transplantation; however, MTN does not support the proposed revision to the Guideline related to additional sample collection 24 hours prior to organ recovery.

In more than 80% of cases, lab technicians test for infectious disease markers when they begin evaluating potential donors for organ allocation. This proposal would increase not only the frequency of testing, but also cost related to the shipping and testing of samples, because the proposed revision would require duplicate testing on more than 80% of cases. Further, MTN argued that the proposed Guideline revision would create operational and logistical complications for OPOs related to obtaining qualified samples, which may be scarce or nonexistent. Typically, qualified samples are not stored by OPOs; rather, hospital labs process these samples, which they may not be willing or able to share, creating another logistical hurdle for OPOs to surmount. Further, donor hospitals can be far from the laboratory that performs donor testing. This geographical distance could be a time- and cost-prohibitive consequence of this proposal, because the delivery of additional donor material to the laboratory may result in increased transportation costs and logistical complexity, especially within the immediate 24 hours prior to organ recovery. Sadly, these additional costs would ultimately be passed onto the recipients awaiting lifesaving transplants and their families.

MTN also expressed its concern regarding the PHS Guideline that requires the labeling of certain organs as “increased risk,” because this label will not result in a reduction in the transmission of infectious diseases. Currently, a donor is designated as “increased risk” in DonorNet® to inform transplant programs of the donor’s risk status. MTN supported the elimination of the “increased risk” terminology for multiple reasons, including the chilling effect on organ acceptance, perceptions that the risk is higher than the true risk for disease transmission, and lack of association between “increased risk” designation criteria and significant risk of HIV, HBV and HCV infection/transmission. MTN argued that eliminating the “increased risk” terminology would avoid restricting the usage of organs from certain donors and reduce the discard of otherwise healthy organs.

Alternatively, MTN argued that the PHS Guideline should be revised to ensure that communication regarding “increased risk” donors is shared with transplant centers in a clear, consistent and systemic manner. Elimination of the “increased risk” terminology would require other means of communication, facilitating informed decision making by the transplant program and their recipients. One suggestion MTN proposed for facilitating this communication was the inclusion of electronic enhancements, such as individual radio buttons (predetermined checklists) in DonorNet relating to the PHS guidelines that might

apply to each donor.

Proposed Revisions to OPOs Conditions for Coverage

Second, MTN commented on the CMS-proposed revisions to OPOs' conditions for coverage. MTN submitted comments in support of CMS' revisions to the term "expected donation rate" as defined in **42 CFR 486.328**.

Previous federal regulations required OPOs to meet two of three outcome measures, one of which measured the percentage of possible donors who become actual donors. The "expected donation rate" for an OPO is based on the national experience for OPOs serving similar hospitals and donation service areas. Federal regulations required that an OPO's observed donation rate metric (number of donors meeting the established donor eligibility criteria per 100 deaths) must not be significantly lower than the expected donation rate for 18 or more of the 36 months of data used for OPO recertification as calculated by the Scientific Registry of Transplant Recipients. MTN supported revisions to the "expected donation rate" language to further define the phrase "significantly lower" and clarify how the standard would be used to establish OPO outcome measures.

Additionally, MTN strongly supported revisions to existing OPO performance metrics. Specifically, MTN supported validation of any new, independently verifiable performance metric. MTN argued that the development of an accurate assessment of donor potential is critical to evaluating OPO performance because, of the nearly 3 million people who die in the United States annually, less than 1% have the potential for organ donation. Currently, OPOs self-report data, like the number of patients eligible to donate organs, and this data is used to calculate outcome measures. Self-reported data is often argued to be unreliable and threatened by self-reporting bias that may be intentionally or unintentionally introduced and can lead to invalid estimations.^[1] For this reason, MTN argued that preexisting outcome measures did not accurately reflect OPO performance due to the self-reported nature of the data used to calculate outcome measures. The standard definition of an eligible donor is subjective, because the definition is not verifiable across all OPOs. MTN advocated for a metric that was verifiable and independently reported by a respected data source to avoid the use of subjective data based on each OPO's definition of an eligible donor.

[1] Alhubaiti A. (2016). Information bias in health research: definition, pitfalls, and adjustment methods. *Journal of multidisciplinary healthcare*, 9, 211–217. doi:10.2147/JMDH.S104807

Callahan Continues: An Update on the Liver Allocation Lawsuit

In April 2019, several Midwestern transplant centers filed suit against the United States Department of Health and Human Services (DHHS) and the United Network for Organ Sharing (UNOS) over a proposed liver allocation policy. The transplant centers also filed a three-count injunction requesting that a judge prohibit DHHS and UNOS from implementing the new liver policy. Judge Amy Totenberg of the U.S. District Court for the Northern District of Georgia ruled against issuing the injunction, and the transplant centers appealed to the 11th Circuit Court of Appeals. On Sept. 25, 2019, the 11th Circuit denied the transplant centers' appeal of Judge Totenberg's initial decision to deny the injunction based on count one of the injunction and remanded the matter back to the District Court to consider the injunction's remaining two counts. On Jan. 16, 2020, after the parties briefed the remaining two counts, Judge Totenberg of the District Court held that the Plaintiffs (transplant centers) failed to show a substantial likelihood of success on the merits of their claims; therefore, the final two counts of the Plaintiffs' motion for a preliminary injunction were denied. However, UNOS has not yet chosen to enforce the new policy.

The transplant centers' lawsuit argues that the new liver policy will "result in hundreds of liver transplant candidates needlessly dying...and at least 20% fewer liver transplants being performed in the most socioeconomically disadvantaged regions in the country." UNOS filed a motion to dismiss this case in May 2019, and on Jan. 21, 2020, Judge Totenberg granted one count of UNOS motion to dismiss establishing that UNOS did not violate a federal regulation (42 C.F.R. § 121.4(b)(1)) which requires the Organ Procurement and Transplantation Network (OPTN) to "provide opportunity for the OPTN membership and other interested parties to comment on proposed policies." Count two of the plaintiffs' petition, which alleges that the Secretary of DHHS violated the Administrative Procedure Act (5 U.S.C. §706(2)) by engaging in "arbitrary and capricious" policymaking "unsupported by substantial evidence" remains ripe for litigation. The lawsuit is in the discovery stage of the litigation process, which requires both sides to exchange and review copious amounts of records to gain knowledge of the important facts of the case, as well as documents that may support the parties' defenses and cause of action.

Bills MTN is Watching in 2020

- **SB 551** — Prohibiting discrimination in insurance against any person based solely on the person's status as an organ donor in Missouri. **[Support]**
- **SCR 33** — Designating August as Minority Organ Donor Awareness Month in Missouri. **[Support]**
- **SB 712** — Modifies provisions relating to anatomical gifts to individuals with

disabilities to ensure that individuals with disabilities receive equal access to donated organs in Missouri. **[Support]**

- **HB 1709** — Adds protections relating to insurance for living organ donors in Missouri so that insurers are prohibited from considering an individual's status as a living donor in the offering, issuance, cancellation, price or conditions of an insurance policy. **[Support]**
- **HB 2228** — Requires lethal injections to be administered in a manner that allows consenting inmates to donate organs. **Oppose** due to logistical and ethical considerations that make condemned inmate donation highly impractical, if not impossible.
- **SB 194** — Amending provisions related to the Kansas Revised Uniform Anatomical Gift Act (UAGA) to allow the adoption of rules and regulations to the UAGA which may be incompatible with existing federal regulations and UNOS policies. **[Oppose]**



On Oct. 29, 2019, MTN hosted a Legal and Governmental Affairs Meet and Greet to discuss MTN's mission, legislative priorities and opportunities for collaboration between

hospital governmental affairs/relations professionals and attorneys who work in hospitals in the Kansas City metropolitan area.

Upcoming Events

- **Feb. 25-27, 2020** — CMS will host a quality conference in Baltimore, Maryland; this meeting is marketed as the preeminent healthcare conference in the nation and has the goal of increasing organ transplantation. Additionally, CEOs and senior leaders from OPOs around the country will focus on developing strategies to decrease the kidney discard rate from 20% to 15%, increase the number of kidney transplants that occur after cardiac death, and empower patients to increase their engagement, understanding and choice regarding kidney transplantation. Two senior leaders from MTN will attend this meeting; those leaders will also be involved in a forthcoming kidney transplant learning collaborative designed to increase the number of kidney donors and transplants as stated in the president's Executive Order on Advancing American Kidney Health.
 - **March 10, 2020** — Kidney Advocacy Day at the Kansas State Capitol in Topeka with the National Kidney Foundation.
 - **June 6, 2020** — MTN will host its fourth annual Donate Life Legacy Walk at the WWI Museum and Memorial in Kansas City, Missouri. MTN will host donor families, transplant recipients, hospital partners and community members in an evening of remembrance. Attendees will enjoy food trucks, live music, yard games, giveaways and a memorial walk to honor organ, eye and tissue donors. Register to attend [here](#).
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Visitors Welcome!

Did you know that MTN loves to host visitors? If you are a legislator or legislative staffer who would like to stop in while visiting your district, please do not hesitate to contact Salama Gallimore (sgallimore@mwn.org) to see MTN's headquarters in Westwood, Kansas.

MTN was happy to host Representative Roger Marshall, MD, and his Health Policy Advisor, Charlotte Pineda, on Aug. 16, 2019. Congressman Marshall and Pineda enjoyed a tour of MTN's tissue suite and laboratory, followed by an informal meeting with MTN's leadership team.



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