



Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.



US Organ Procurement Organization Donation Principles, Laws, and Practices

Thomas Mone and Gabriel Danovitch

US organ procurement organizations (OPOs) are the world's donation leaders,^{1,2} with 109 deceased donor transplantations per million population and a 38% increase in donations during the past 5 years (from 8,596 deceased donors in 2014 to 11,870 in 2019).^{3,4} This growth has helped decrease waiting lists by 10% during the past several years despite an increase in the prevalence of kidney failure.⁵ During the 2014 to 2019 period, donations have increased in 91% of the 58 OPOs (Table S1), with those achieving the greatest growth showing increases \geq 165% (Table 1). These changes are statistically independent of OPO geographical size, population, death rate, region, race/ethnicity, and leadership tenure.³ Although OPO population and potential donor demographics differ dramatically,⁶ donation growth rates and number of donors are within 1.5 standard deviations of the mean for 90% of OPOs, reflecting that they all share the legal and operational principles and practices described here.

Donation Law

US organ donation practice is founded on 2 laws: the National Organ Transplant Act (NOTA)^{7,8} and the Uniform Anatomical Gift Act (UAGA).⁹ NOTA defines the federal oversight of OPOs, by the Centers for Medicare & Medicaid Services (CMS) and the Organ Procurement and Transplant Network, through its contractor the United Network for Organ Sharing (UNOS). Along with NOTA, each state has adopted a version of UAGA that provides OPOs the legal guidelines by which organ donation occurs, including the legally binding status of donor registrations and the hierarchy of donation decision makers.⁹

OPO Certification by CMS

Per NOTA, CMS designates the service area of each of the 58 OPOs (Fig S1) and assesses their performance every 4 years. In 2019, CMS issued proposed regulations intended to increase donation rates of all OPOs to match the current top 25th percentile rate or be

decertified,¹⁰ with projections indicating that nearly 60% of US OPOs would be decertified if the proposed regulation were enacted. The rules create a metric that relies on data from death certificates filed with the US Centers for Disease Control and Prevention (CDC) and project 272,000 potential donors in US hospitals,¹⁰ an estimate that is 14 times greater than current estimates based on hospital records. This dramatic difference is because CDC death certificates do not include comorbid conditions that did not cause death (such as unrelated cancers) and include no identification of brain death or severe neurologic injury compatible with donation after circulatory death (DCD).¹¹ Further, around 30% to 60% of cause-of-death statements are reported to be inaccurate.¹²⁻¹⁴ Additionally, the rule assumes a uniform demographic distribution in prevalence of diseases that allow for or rule out donation (an assumption that the CDC data refute and the recent experience with COVID-19 demonstrates to be inaccurate), as well as assuming uniform racial and ethnic authorization rates, despite Scientific Registry of Transplant Recipients data showing statistically significant variance in donation rates by race across the country. Thus, assessing OPO performance against this proposed measure is likely to be statistically unreliable and may actually result in decertifying OPOs that are high performing in demographically challenged areas. Such a statistically unsupported disruption of the world's leading donation system would be highly problematic, even though the underlying goal of continued significant improvement in donation is universally supported, as are efforts to develop a reliable metric that will prompt continued growth in donation. The U.S growth to date and opportunities for continued growth are built on the following practices.

Public Education and Donor Registries

Public education ensures that an individual's first exposure to organ donation occurs before the sudden loss of a family member and includes paid advertising; newsletters and social

FEATURE EDITOR:
Daniel E. Weiner

ADVISORY BOARD:
L. Ebony Boulware
Kevin Erickson
Eduardo Lacson Jr
Bruce M. Robinson
Wolfgang Winkelmayr

Policy Forum highlights aspects of nephrology relating to payment and social policy, legislation, regulation, demographics, politics, and ethics, contextualizing these issues as they relate to the lives and practices of members of the kidney community, including providers, payers, and patients.

Table 1. The Top 10 OPOs With Greatest Increase in Donors From 2014 to 2019

	2017 Population (million)	2017 Deaths (thousand)	2019 Donors Per 10,000 Deaths	Observed/Expected Ratio ^a	Donor Increase 2014 to 2019
All donation service areas	330.8	2,844	42	1.00	138%
FLFH OurLegacy	4.2	39	50	0.89	251%
AZOB Donor Network of Arizona	7.2	59	53	0.95	199%
CORS Donor Alliance	6.2	43	44	1.06	174%
NVLV Nevada Donor Network	2.4	19	87	1.17	173%
MOMA Mid-America Transplant Services	4.7	48	56	0.92	170%
OHLP Lifeline of Ohio	3.5	32	44	0.99	169%
CTOP LifeChoice Donor Services	2.5	23	31	0.89	167%
NJTO New Jersey Sharing Network	7.1	59	35	0.93	165%
SCOP We Are Sharing Hope South Carolina	4.9	48	38	0.90	165%

Note: Based on data from the Association of OPOs, Organ Procurement and Transplantation Network, Scientific Registry of Transplant Recipients, and Centers for Disease Control and Prevention.^{2,4} A complete listing of OPOs and donation statistics is available in [Table S1](#).
Abbreviation: OPO, organ procurement organization.

^aBased on Scientific Registry of Transplant Recipients data from July 2018 through June 2019.

media; outreach to religious, business, and public communities; and promotion at motor vehicle departments, where donor registries are linked to driver license renewals.¹⁵ The United States' legally binding registration is unique and has been a critical element of donation growth, with registered donors increasing 160% during the past 12 years, from 60 million¹⁶ in 2007 to 156 million¹⁷ in 2019.

Professional Education

OPO Donation Development Coordinators ensure that hospital staff are informed of the legal and clinical aspects of donation and verify that they refer potential donors to the responsible OPO, whose role is formally established in a CMS-required affiliation agreement. CMS gives the OPO the right to perform chart reviews, seek family authorization, manage deceased donors, and perform organ recovery within all Medicare-funded hospitals.

Donor Identification

OPOs assess thousands of referrals of possible donors (those with major neurologic injuries and on mechanical ventilator support), of whom <10% are ultimately declared brain dead or eligible for DCD and are without contraindicated medical conditions. Upon referral, OPO call centers perform an initial assessment, a process that rules out ~20% of cases because of advanced age and transmittable diseases. OPOs then routinely dispatch staff for on-site assessment within 1 to 2 hours of referral.

All donors must be on mechanical ventilator support to maintain circulation to the organs up to the time of recovery. In the United States, 75% to 85% of deceased donors had organs recovered after having been declared brain dead, with the rest having met DCD criteria. The rarity of these circumstances has been estimated at 0.6% of

all deaths,¹⁸ approximately 18,000 of the 2.8 million annual deaths across the country.

Individual/Family Authorization

Donation requires prior registration by individuals or post-mortem authorization by family members or their agents. OPO Family Care or Procurement Coordinators provide emotional support, clinical information, and an outlet for grief, a process that has been associated with improved rates of donation.¹⁹ Current US organ donation family/donor authorization rates average 70% (75% for "eligible" donors as reported by UNOS and 60% for DCD donors as reported by OPOs), a rate of participation unmatched in other types of donation (eg, <10% of potential blood donors actually donate²⁰).

Donor Management

Donor management begins when the Procurement Coordinator takes over the clinical treatment of an authorized donor and spends 24 to 60 hours or more reducing the insult of brain death to the organs and assessing organ function. As such, Procurement Coordinators receive donor management training via Advanced Practice Procurement Coordinators, medical professionals, professional societies, and OPOs.

Organ Allocation and Placement

Placing organs with listed recipients, per UNOS-generated lists and policies, is performed by the Procurement Coordinator in the hospital ICU or dedicated "Allocation Coordinators" at the OPO, allowing the Procurement Coordinator to focus on improving organ function. Since 2014, all offers are made through the UNOS DonorNet system, which provides web-based access to critical clinical data and imaging to aid acceptance.²¹ In 2019, the UNOS

Organ Center began a pilot project designed to accelerate the placement of extremely hard-to-place kidneys.²² This and related changes are intended to help US kidney transplantation centers expand their acceptance criteria to match international practices, which is estimated would enable 1,500 to 2,000 additional US donors annually.⁶

Organ Recovery

Organ recovery (no longer called “harvesting”) occurs 24 to 60 hours after authorization, when recovery surgeons converge on the donor hospital operating room. OPO perioperative surgical recovery staff ensure that the recovery surgeons have current credentials, all necessary equipment is in the operating room, the recovery procedure is properly documented, and that all donor-related documentation accompanies each recovered organ. In nearly 20% of OPOs, this step has shifted from donor hospitals to free-standing OPO-operated recovery centers, which have been shown to increase organ recoveries and reduce biological contamination of tissues recovered.²³

Aftercare

US OPOs provide donor families with aftercare services, a practice that is designed to refer donor families to community resources, as well as professional grief and family support counseling to assist in grief recovery.²⁴ Donor remembrance ceremonies, support groups, and opportunities to become volunteer ambassadors provide donor families the emotional support of sharing experiences with other donor families and the opportunity to share their personal stories of gratitude at the chance to leave a legacy of life from their loved one’s death. In doing so, they advance the public education and donation promotion mission of the OPO.

Information Technology

Organ donation occurs across broad geographical regions. Sophisticated telemedicine capability is essential for OPO Electronic Donor Records to capture and communicate donor data to enable donor management consultation, organ allocation by UNOS, and provide transplant teams more granular clinical data and imaging than the abbreviated UNOS DonorNet summaries.

Quality Assurance

Rigorous requirements for 100% case review processes imposed by the US Food and Drug Administration²⁵ on tissue recovery programs have had the beneficial effect of enhancing oversight of organ recovery, as has case-by-case review of all organ offers and potential donor-derived disease transmission events by UNOS. This oversight has added to the reliability of organ recovery, allocation, and transplant practices and public trust that is essential for donation.

Financial Management

The US OPO system is unique for its fee-for-service model in which OPOs submit invoices to transplantation centers for the costs of organ recovery. OPOs’ Standard Acquisition Charges (a CMS term that was coined for the process of determining kidney charges²⁶ and is now used as a terminology for all organ fees) range from \$30,000 to ≥\$60,000, largely based on the complexity of organ testing and cost of living in local areas. This fee-for-service methodology has allowed OPOs to fund investments that have been instrumental in donation growth.

Human Resource Management

Recruitment, training, and retention of highly specialized clinical, family care, donation development, and public education staff is challenged by the rarity of these skills. Thus, OPOs rely on in-house and contracted specialty training.

Conclusion

Adoption of the principles and practices described here has been essential to the success of organ donation in the United States, its recognition as a vital component of the health care system, and its necessary continued growth. The need for a life-saving transplant could affect any one of us: organ donation is an essential part of the social compact that creates and nurtures community and life itself.

Supplementary Material

Supplementary File (PDF)

Figure S1: Map of the service areas for US OPOs.

Table S1: OPO data for population, deaths, donations, and increase in donations, 2009-2019.

Article Information

Authors’ Full Names and Academic Degrees: Thomas Mone, MS, and Gabriel Danovitch, MD.

Authors’ Affiliations: OneLegacy (TM); and Kidney and Pancreas Transplant Program, David Geffen School of Medicine, University of California at Los Angeles, Los Angeles, CA (GD).

Address for Correspondence: Thomas Mone, MS, OneLegacy, 221 S Figueroa St, Ste 500, Los Angeles, CA 90012. E-mail: tdmone@onelegacy.org

Support: None.

Financial Disclosure: The authors declare that they have no relevant financial interests.

Peer Review: Received December 1, 2019, in response to an invitation from the journal. Evaluated by 3 external peer reviewers, with direct editorial input from the Feature Editor and a Deputy Editor. Accepted in revised form May 26, 2020.

Publication Information: © 2020 by the National Kidney Foundation, Inc. Published online September 25, 2020 with doi [10.1053/j.ajkd.2020.05.022](https://doi.org/10.1053/j.ajkd.2020.05.022)

References

1. Glazier A, Mone T. Success of opt-in organ donation policy in the United States. *JAMA*. 2019;322(8):719-720.
2. Global Observatory on Donation and Transplantation. Summary. <http://www.transplant-observatory.org/summary/>. Accessed May 7, 2020.
3. Organ Procurement and Transplantation Network. National data. <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>. Accessed May 7, 2020.
4. United States Census Bureau. Quick facts. <https://www.census.gov/quickfacts/fact/table/US/PST045219>. Accessed May 7, 2020.
5. Saran R, Robinson B, Abbott KC, et al. US Renal Data System 2019 Annual Data Report: epidemiology of kidney disease in the United States. *Am J Kidney Dis*. 2020;75(1)(suppl 1):S1-S64.
6. Sheehy E, O'Connor K, Luskin R, et al. Investigating geographic variation in mortality in the context of organ donation. *Am J Transplant*. 2012;12(6):1598-1602.
7. Pub L No. 98-507, 98 Stat 2339. <https://www.govinfo.gov/content/pkg/STATUTE-98/pdf/STATUTE-98-Pg2339.pdf>. Accessed May 7, 2020.
8. National Organ Transplant Act, 42 USC §274 (1984). <https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section274&num=0&edition=prelim>. Accessed May 7, 2020.
9. Organ Donation and Transportation Alliance. UAGA. <https://organdonationalliance.org/resources/uaga/>. Accessed May 7, 2020.
10. Centers for Medicare & Medicaid Services (CMS). HHS. Medicare and Medicaid Programs: Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organization. *Fed Regist*. 2019;84(246):70628.
11. National Center for Health Statistics, Centers for Disease Control and Prevention, US Department of Health and Human Services. Instructions for completing the cause-of-death section of the death certificate. https://www.cdc.gov/nchs/data/dvs/blue_form.pdf. Accessed May 7, 2020.
12. McGivern L, Shulmann L, Carney JK, Shapiro S, Burdock E. Death certification errors and the effect on mortality statistics. *Public Health Rep*. 2017;132(6):669-675.
13. Pritt BS, Hardin NJ, Richmond JA, Shapiro SL. Death certification errors at an academic institution. *Arch Pathol Lab Med*. 2005;129(11):1476-1479.
14. Smith Sehdev AE, Hutchins GM. Problems with proper completion and accuracy of the cause-of-death statement. *Arch Intern Med*. 2001;161(2):277.
15. Razdan M, Smith J, Bryce C, Degenholtz HB. Promoting organ donor registries through public education: what is the cost of securing organ donors? *Transplantation*. 2016;100(6):1332-1338.
16. Donate Life America. 2011 Annual Update. Richmond, VA: Donate Life America; 2011.
17. Donate Life America. 2019 Annual Update. Richmond, VA: Donate Life America; 2019.
18. Neurocritical Care Society. Brain death: frequently asked questions for the general public [2016]. <https://bioethics.yale.edu/sites/default/files/files/Brain%20Death%20FAQ%20-%20final%20posted.pdf>. Accessed May 7, 2020.
19. Shemie S, Robertson A, Beitel J, et al. End-of-life conversations with families of potential donors. *Transplantation*. 2017;101(5)(suppl):S17-S26.
20. American Association of Blood Banks. Blood FAQ. <http://www.aabb.org/tm/Pages/bloodfaq.aspx>. Accessed May 7, 2020.
21. Organ Procurement and Transplantation Network. How organ allocation works. <https://optn.transplant.hrsa.gov/learn/about-transplantation/how-organ-allocation-works/>. Accessed May 7, 2020.
22. UNOS News Bureau; Organ Procurement and Transplantation Network. Kidney Accelerated Placement project for national offers begins July 18. <https://optn.transplant.hrsa.gov/news/kidney-accelerated-placement-project-for-national-offers-begins-july-18>. Accessed May 7, 2020.
23. Doyle M, Subramanian V, Vachharajani J, et al. Organ donor recovery performed at an organ procurement organization-based facility is an effective way to minimize organ recovery costs and increase organ yield. *J Am Coll Surg*. 2016;222(4):591-600.
24. Gift of Hope. Changing tragedy into triumph: aftercare specialist. <https://www.giftofhope.org/changing-tragedy-into-triumph-aftercare-specialist/>. Accessed May 7, 2020.
25. US Food and Drug Administration. Tissue & tissue products. <https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products>. Accessed May 7, 2020.
26. Centers for Medicare & Medicaid Services, Department of Health and Human Services. Medicare Provider Reimbursement Manual. Part 1 - Chapter 31, Organ Acquisition Payment Policy. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R471pr1.pdf>. Accessed May 7, 2020.