
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 ≥ 165% (Table 1). These changes are statistically independent of OPO geographical size, population, death rate, region, race/ethnicity, and leadership tenure.5 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 OPO geographical size, population, death rate, region, race/ethnicity, and leadership tenure.5 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.

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
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 million 17 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

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

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

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.
Organ Center began a pilot project designed to accelerate the placement of extremely hard-to-place kidneys. 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.⁷⁻⁸

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.⁹ 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 Administration 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 charges 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.

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