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Success of Opt-in Organ Donation Policy in the United States

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Organ donation in the United States is governed by state law through the Uniform Anatomical Gift Act (UAGA) based on gift law rather than informed consent principles (donation presents neither risks nor benefits to the deceased donor). This allows a legally binding transfer of a gifted organ from donor to recipient based on donative intent, transfer, and acceptance. The UAGA state laws align with US opt-in practices, in which permission is granted either by the donor in advance of death (such as designated on a driver's license) or the donor's surrogate at the time of death and affirmatively provides donative intent required for a legally valid gift that can be acted upon. Over that past 5 years, the United States has experienced a 30% increase in deceased organ donors, from 8269 in 2013 to 10 722 in 2018,¹ although the number of organs available for transplant still does not come close to meeting the increasing need.

Pathways to US Organ Donation: Opt-in Policies and Practice

The US practice of opt-in donation presents 2 opportunities for organ donation. The primary path to donation in the United States is through donor registries and is uniquely successful compared with other countries, with more than 152 million registered donors, representing 54% of the US adult population.² A registered individual provides legally binding permission for donation at the time of death, and family does not have the right to override this decision. Current US practice is to proceed with a registered donation if medically suitable, even over family objection.³ The ability to move forward based on the donor's affirmative decision is ethically supported and consistent with autonomy as a central principle in US health care decision-making. It is also in alignment with successfully maximizing opt-in policy and the UAGA state laws. The second path to donation in the United States is surrogate authorization of organ donation from an unregistered individual (ie, who has not registered as an organ donor) at the time of that individual's death. The successful implementation of US opt-in is thus accomplished by a legal framework that is well-aligned with donation practices.

Proposals to Consider Opt-Out Organ Donation Policies

With the continued shortage of organs for transplant in the United States, the call to adopt opt-out "presumed consent" donation policies has been made repeatedly over the past several years with proposed legislation to amend the UAGA state laws in California, Connecticut, Colorado, Delaware, Massachusetts, New Jersey, New

York, Texas, and Vermont, although none of these efforts have ultimately passed.

These US legislative efforts often point to an international experience with opt-out organ donation (the approach in 17 of 41 publicly reporting countries with mature donation programs), relying on presumed consent for organ donation unless an individual has registered a refusal to donate. Proponents of an opt-out system for the United States may have some misunderstandings about the performance and utility of the current opt-in US system. Requiring an affirmative donation decision through opt-in policies is also aligned with the US's cultural emphasis on individual rights and autonomy principles that is not achieved in the opt-out international experience. As identified below, the US opt-in system donation rates routinely exceed those of the best performing opt-out international countries.

Donation Rate Measurement

Current US donation regulations evaluate performance based on donors per potential eligible donor; a metric that incorporates a data set of in-hospital, mechanically ventilated, neurologically injured, and medically suitable potential organ donors.⁴ Other countries have not adopted this detailed metric and therefore the most reliable measure for comparison is donors per 10 000 deaths. This measure is calculated as the total number of actual deceased donors in the numerator and total deaths divided by 10 000 in the denominator using government reported data sets. Organ donation performance in international donation jurisdictions ranked by this measure according to opt-in or opt-out laws is shown in the eTable in the [Supplement](#). Because organ donation in the United States is governed by separate state laws, individual states (many of which are larger than reporting countries) are listed alongside international countries. The eTable does not list organ procurement organizations (OPOs) because OPO-designated service areas do not align with US state boundaries, which are the legal jurisdictions relevant to comparing opt-in and opt-out laws.

In 2018, the US overall organ donation rate was 38.1 donors per 10 000 deaths, second among reporting countries only to Spain (which has an opt-out donation policy). Six individual US states had rates that were higher than Spain, and US states comprised 43 of the top 50 jurisdictions. Furthermore, in the opt-in jurisdictions, the mean donation rate was 27% higher than rates in opt-out jurisdictions (32.6 vs 25.6 donors per 10 000 deaths, respectively). The data demonstrate that opt-in policies in the United States are associated with higher organ donation rates than some countries with opt-out policies as the legal default. The foundation of this coun-

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ter-intuitive result is the unique alignment of culture, law, and practice in the US implementation of opt-in policies.

The Practice of Opt-Out Donation

Opt-out as a possible strategy to increase donation in the United States has been based on findings of statistically significant increases in donation within countries with low donation rates that switched to an opt-out policy.⁵ There are no reports, however, of a country moving to an opt-out policy and increasing its donation performance to achieve average or higher international donation rates.

Spain as a leader in organ donation with an opt-out law, attributes its success not to opt-out laws but rather to a well-funded, nationally promoted, commitment to donation integrated into a nationalized hospital system and practice.⁶ Comparable performance in the United States with hospitals required to refer potential donors to the coordinated network of not-for-profit OPOs is consistent with this conclusion. With the United States as 1 of the 2 top-performing donation countries, there is no evidence that switching to an opt-out system would have the desired beneficial effects of increasing organ donation rates, and based on the mean donation rate in opt-out jurisdictions, it could potentially adversely affect donation performance.

In contrast to US opt-in policies in which the donation rate is a composite of 2 pathways, opt-out systems have only 1 pathway to "yes" (ie, the default policy) and 2 pathways to "no"—if the individual opted out or if the family objects to donation, because opt-out countries will not proceed with organ donation over family objection.⁷ If the US moved to a similar opt-out policy, the percentage of potential donors opting out combined with family objections would need to be quite small to realize any gains in donation

performance. There is also the real potential for the donation rate to decline; as evidenced in Wales, which continues to have below average international levels and most recently in the Netherlands where an increasing number of people (currently 31%) have opted-out.^{5,8}

Individual Rights-Based Culture

The US culture is deeply steeped in individual rights through many laws and societal norms prioritizing individual autonomy. Rights-based cultures are inconsistent with opt-out policies founded in utilitarian and social contract concepts. Ethical and legal challenges to opt-out legislation as an unwarranted or unconstitutional government taking could pose a significant risk and presents an opportunity cost that switching from opt-in could result in legal uncertainty and backlash resulting in declining donation rates if significant portions of the population opt out.⁹ Experience from other countries that have switched to opt-out highlights the potential for this negative unintended consequence.⁹

Conclusions

The United States has experienced significant growth in deceased organ donors and continues to have one of the best donation rates in the world. Nevertheless, the critical need for organ transplant is not met. International data suggest that the most effective donation authorization strategy for the United States is to build on the current opt-in system that demonstrably works, and to increase the number of registered donors from today's 54% to 75% or higher. Doing so would be an accomplishment that would increase available organs for donation and save thousands of lives.

ARTICLE INFORMATION

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