Presumed Consent
Resource Document

The waiting list for organ transplants exceeds 110,000 people and grows roughly 10% a year, despite more than 28,400 transplants being performed annually. With the aging population and an obesity epidemic, the gap between those who need transplants and the number of organs available will get worse. While prevention and medical innovation can, in the long run, reduce the need for organ transplant, these measures will not help those suffering from organ failure today.

This clear-cut need prompts legislators and citizens to question whether the United States' system of voluntary organ donation should be replaced by an opt-out system of donation (often called “presumed consent”) where one is deemed to be a donor unless he or she takes action not to be. It is a fair question, worthy of careful consideration. The analysis shows, however, that changing our donation laws to an opt-out system is unlikely to increase actual donation rates. In addition, it could be subject to significant legal challenge and would eliminate an important part of our current voluntary opt-in system that has significantly increased donation.

1. Would more organs be available for transplant in the U.S. if we were all considered donors unless we specifically opt-out, as in some European countries?

The facts suggest otherwise. Today, under our voluntary, opt-in system, 75% of Americans who meet the criteria to donate actually become organ donors after their death (by comparison, only 7% of people who are eligible to donate blood actually do so). This results in over 25 organ donors per million population, which is the second highest organ donation rate in the world after Spain. Contrary to common belief, Spain also relies on an opt-in, voluntary donation system. Major European countries with opt-out laws have donation rates that range from 11.4 to 20.6 organ donors per million, which is well below the U.S. See Table A.

The data suggests that social, cultural, and operational factors, rather than legal structures, are the key to increased donation rates. According to a comprehensive statistical study of PC by the British National Institute for Health Research, “presumed consent alone is unlikely to explain the variation in organ donation rates between different countries.” Similar findings were recently published that again underscored that presumed consent laws do not directly correlate with increases in donation rates.

The international data show that opt-out donation laws are not the answer to the organ shortage in the U.S. and would be unlikely to actually increase donation rates.
2. What are the legal challenges that opt-out donation laws may face?

The Uniform Anatomical Gift Act (UAGA) is the model statute adopted as state law in the U.S that governs how organs can be donated after death in our uniformly voluntary opt-in system.\textsuperscript{xi} Organ donation under the UAGA is based on gift law principles. Changing to an opt-out system would conflict with the UAGA because evidence of donor “intent” is a required legal element for a gift to be binding. In an opt-out system, however, the default is that an individual is a donor if no action is taken. The legal issue is whether “donor intent” can be met on the basis of inaction. This conflict with gift law could lead to legal challenges to anatomical gifts made under an opt-out system. One could consider restructuring the organ donation laws outside of gift law principles but this would be a fundamental legal change that could not be accomplished with a simple statutory amendment to the UAGA. Further, eliminating gift law as the basis for organ donation could have unintended consequences such as undermining the legal foundation that prohibits the buying and selling of organs.

Other legal issues could include constitutional challenges, such as whether an opt-out donation law would amount to a government “taking” or violate substantive due process by interfering with the fundamental right to burial. As a more general matter, the laws in our country are built heavily on the core concepts of individual rights and liberties. Opt-out donation may be contrary to these fundamental legal principles and unprecedented in U.S. law.

The need for uniformity and legal clarity regarding how organ donation can be authorized and the binding nature of an anatomical gift has been recognized since the UAGA was first enacted in 1968. Legal uncertainty about U.S. organ donation laws would be detrimental to our system of transplantation. Medical teams must rely on the legal status of an organ donation under critically short time frames. Legal challenges to opt-out legislation would be complex and time-consuming with the potential for tremendous harm by undermining confidence in our system of organ donation and transplantation.

3. Would there be unintended consequences in the U.S. if the country changed to an opt-out donation system?

One of the benefits of our voluntary opt-in system is that it allows, but does not require, an individual to make a donation decision prior to death. If an individual does not register as an organ donor (or document a refusal to be a donor), the individual’s family can make a donation decision at the time of his or her death. What this means is that there are two opportunities for donation to be authorized under our voluntary opt-in system; either by the individual’s prior donor registration or by the family’s decision to donate at the time of death. This accounts for the difference between the 37%\textsuperscript{xii} of Americans who register to be donors through their respective state registries and the 75% who actually become organ donors at the time of death.

When confronting the need to make final decisions, the vast majority of families choose to donate. This is a significant difference from opt-out donation systems where there is no such
opportunity to address misinformation and inspire families to donate; the decision to opt-out is a legally binding refusal to donate that family cannot override.

The significance of misinformation is not merely anecdotal; the 2010 Donate Life America/Astellas independent\textsuperscript{xiii} poll found that a shocking 52\% of people incorrectly believe that doctors may not try as hard to save their lives if the doctor knows the patient wishes to be an organ or tissue donor, and that a remarkably high 61\% mistakenly believe it may be possible for a brain dead person to recover from his or her injuries. With these serious misconceptions among a large proportion of the US population, it is a realistic concern that changing to an opt-out donation system may lead to millions of ill-informed decisions to opt-out with no chance to address these misconceptions when the opportunity to donate actually occurs. Furthermore, research shows that there is very little public support for an opt-out organ donation law.\textsuperscript{xiv} Given this lack of public support and the misconceptions that exist, a realistic unintended adverse consequence that could occur if an opt-out system were implemented is a significant drop from the current U.S. rate of organ donation.

4. What are alternatives to increase donation?

Currently the 58 non-profit Organ Procurement Organizations in the United States successfully facilitate donation for three quarters of those who can actually donate organs in order to save tens of thousands of lives each year. Reaching the remaining 25\% of non-donors in the United States will not be achieved by changing the legal organ donation default to an opt-out system; the data and research show opt-out systems are likely to be less effective and to raise significant legal challenges that will undermine donation.

According to Rafael Matesanz, the head of Spain’s system of donation and transplantation, one answer lies in Spain's highly structured and managed transplant coordination network with intensive care transplant coordinators based at the site of the donation. This “in-house coordinator” system utilized in Spain is one example of a way in which donation can be increased. Uniformly implementing this technique in U.S. hospitals has the potential for increasing the rate of donation in the U.S.

Other best practices, where consistently implemented, that have shown to increase donation include efforts to optimize donor registries through focused public education and systematic collaboration between the organ donation professionals and hospital leadership. Successful national initiatives by the U.S. Department of Health Resources and Service Administration to increase organ donation have concentrated on these strategies.\textsuperscript{ xv} Recent alignment with the American Hospital Association promises to provide similar gains to donation by linking Organ Procurement Organizations with state hospital associations to develop collective donation goals as a key component to effective collaboration.
Ultimately, it is the recognition that organ donation is a shared responsibility among health care professionals, cultural and religious leaders and the public alike that will bring us to the day where no one dies for lack of an organ transplantation.

4 USDHHS-HRSA-Department of Transplantation/Alliance for Organ and Tissue Donation/OPO Quarterly Data Snapshot March 2010
9 A Rithalia, C McDaid, S Suekarran, G Norman, L Myers and A Sowden* A systematic review of presumed consent systems for deceased organ donation Health Technology Assessment 2009; Vol. 13: No. 26 DOI: 10.3310/hta13260
### Table A.

<table>
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<tr>
<th>Country</th>
<th>Consent Practice</th>
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<tr>
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<td>PC</td>
<td>25.3</td>
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VC = Voluntary Consent Practice, PC = Presumed Consent Practice

DPMP Data Sources:


