

# Virtual Mentor

Ethics Journal of the American Medical Association  
September 2005, Volume 7, Number 9

## Policy Forum

### **Presumed vs Expressed Consent in the US and Internationally**

by Sheldon Zink, PhD, Rachel Zeehandelaar, and Stacey Wertlieb, MBe

The shortage of organs available for transplant has been a serious and unchanging worldwide problem since such surgeries were first made feasible and safe several decades ago. Nations around the world have relied on different strategies to try to alleviate this problem with varying levels of success.

The United States' system for organ procurement operates under a model of expressed consent. This means that an individual will *not* be an organ donor unless he or she explicitly states otherwise. The desire to be a donor is typically noted on a driver's license, in an advance directive, or by a surrogate with decision-making responsibility. While maintaining the autonomy of potential donors, the expressed-consent model has not been shown to be effective in increasing the supply of organs to a level anywhere near that of the demand.

In contrast, some countries have relied on a method of *presumed* (rather than *expressed*) consent for organ procurement. This model takes the opposite assumption for granted—individuals are presumed to want to donate their organs upon brain death unless they have expressly objected to doing so. Every country has a slightly different policy, but in all forms of the model consent can be presumed only when individuals are properly informed of the policy and given the opportunity to opt out of donating [1]. A short review of the policies employed by different countries follows.

#### **International Presumed Consent Policies**

With 33.5 out of every 1 million residents having organs that are in a condition that allows them to be transplanted after death, Spain has the world's highest rate of actual donation [2]. Spain's presumed-consent law was passed in 1979 and requires the prospective donor to be declared dead on neurological criteria ("brain dead") by 3 physicians [3]. Once death has been declared, any individual who has not formally registered an opposition is considered a potential donor. This system, combined with a societal respect for organ donors, has contributed to Spain's successful organ procurement program [4]. Moreover, the presumed-consent policy in Spain is cost-effective, saving the National Health Service more than 200 000 euros in medical costs for each kidney transplant preformed on a patient on dialysis [2].

A similar presumed-consent law was passed in Belgium in 1986 and implemented in 1987 [3,5]. If an individual does not want to donate, he or she is required to register the objection with the Central Health Authority. Prospective donors can change their decision at any time [6]. While physicians in Belgium are under no obligation to ask

the prospective donor's family for permission to recover the organs, or even to inform them of their intention to do so, if a family member explicitly opposes organ recovery, the physician cannot proceed [6]. Consent is presumed not only for Belgian citizens, but for anyone who has lived in the country for 6 months or more [6]. After widespread educational efforts and almost 20 years' experience since the policy was implemented, less than 2 percent of the Belgian population has registered an objection to organ donation [5].

Other countries with presumed-consent policies include Austria, France, Columbia, Norway, Italy, and Singapore. In Austria, the rate of donation quadrupled within 8 years of a presumed-consent policy's being introduced [3, 6]. Under Austrian legislation, organs can be recovered irrespective of relatives' objections [7]. Today, the procurement rate in Austria is twice as high as those in the United States and most of Europe, with the number of kidney transplants performed nearly equal to the number of people awaiting donor kidneys [4].

Other policies for organ donation include the Caillavet Law of France passed in December 1976, which allows a third party to state whether the potential donor had objections, even if the donor himself had not registered them [4]. A Columbian law states: "There shall be a legal presumption of donation if a person during his lifetime has refrained from exercising his right to object to the removal from his body of anatomical organs or parts during his death [8]." In Norway, organs may be removed after the relatives have been informed of the intention to remove them, and only the immediate next-of-kin can halt procurement by withholding consent [7]. Contrastingly, in Italy, despite presumed-consent laws, organs may only be removed once it has been determined that the donor's relatives do not object [7]. Lastly, in Singapore a presumed-consent law has been in effect since 1987 [9]. All residents receive a letter when they reach the age of 18 that states they are presumed to consent to organ donation unless they explicitly object to it. The only exceptions to this policy are Muslims, who are automatically considered objectors unless they opt in [9]. Countries with presumed consent have generally seen higher rates of organ donation than countries with expressed consent such as the United States. In fact, when Denmark switched from presumed to expressed consent in 1986, donation rates fell by 50 percent [3].

It is interesting to note that most countries that have presumed-consent laws also have national health care or a system that combines some universal health care with some private care. In the United States, the government pays for transplants of kidneys but not of other organs. In a country with private health care, only those with insurance would be eligible (or able to afford) other transplants, whereas in countries where consent is presumed and health care is universal, all citizens are eligible to receive these transplants.

### **International Expressed-Consent Policies**

The United States and Denmark are not the only countries to operate under a model of expressed consent; the United Kingdom, Canada, and Brazil, for example, do also. A Gallup poll found that 70 percent of the US respondents said they wanted to donate

their organs; however, the proportion that are registered to do so is significantly lower [10]. Similarly, in the UK, only 15 percent of the public formally join the National Health Service Organ Donation Register [11], despite public opinion polls that suggest an increasing support for a change to presumed consent. The British Medical Association believes this shift is “not only feasible in this climate, but is also the right and morally appropriate thing to do” [11].

Brazil adopted a presumed-consent policy in 1997, but it was quickly repealed, and the country returned to a policy of expressed consent after the Brazilian Medical Association and the Federal Council of Medicine criticized the law and claimed that “most doctors were unwilling to remove the organs without family consent, even if the law demanded them to do so” [4].

If presumed consent has been more successful than expressed consent worldwide, why haven't all countries made the transition in organ procurement policies? Should the United States switch to a model of presumed consent, and if so, would it work here? There are strong arguments on both sides of the ethical question.

### **Ethical Arguments**

A primary objection of those who oppose implementing a presumed-consent policy in the United States is a claim of the loss of patient autonomy. Many physicians and bioethicists believe that it is wrong to invade someone's body without that person's consent [12] and that “absolute respect for the will of the deceased” is necessary [6]. Furthermore, Kennedy et al argue that the state is already too involved in our lives, and “further incursion into our affairs by assuming possession of our body parts... would be a step too far” [7]. The authors also wonder whether implementation of a presumed-consent law would cause such social unease that people would turn away from organ transplantation entirely, although this has not come to pass in other countries [7].

Some objectors to presumed consent employ a Constitutional argument to support their stance, stating that such a law would violate the 5th Amendment prohibition on taking private property without due process and just compensation [13]. Objectors also mention the possibility of “false positives”; that is, presuming someone consented when in actuality he or she did not want to donate, had not read the necessary materials, did not know the relevant facts, or was otherwise unable to participate in the debate over organ donation [14].

On the other side of the argument are those who believe the United States should adopt a system of presumed consent for organ procurement. They respond to the argument over a loss of autonomy by countering that a presumed-consent model actually provides more autonomy than expressed consent because it allows the donor, not his or her family members, to make the final decision [3]. They maintain that asking a family for a loved one's organs at a time of intense grief is cruel and unnecessary and that, by presuming consent, the family's anxiety over this decision is alleviated [14,15].

Supporters of presumed consent also employ a utilitarian argument as support for implementing such a policy. Meredith Watson claims that presumed consent provides the greatest good for the greatest number of people by harming no one and benefiting many [16]. She adds that the burden of communicating and registering preference should fall on those who object to donating, not those who support it, because the goal of transplantation is one that is socially desirable [16]. Dr Michael Gill believes that this would also increase accuracy, inasmuch as objectors are more likely to register their opposition than supporters are to sign up as donors. Following this argument, there would be fewer mistakes in interpreting a potential donor's wishes [12]. To conclude this line of reasoning, Gill suggests that all mistakes in interpreting a donor's preferences have the same moral worth; it is no worse, Gill says, to assume that someone wants to donate, take his or her organs, and then find out that he or she objected than to wrongly assume that someone did not wish to donate and therefore forgo potential organs [12]. In response to this claim, objectors to a presumed-consent model argue that these 2 types of mistakes do not have the same moral worth; mistaken removals are inherently worse than mistaken nonremovals [12].

### **Conclusion**

It seems unlikely that the United States will make the transition to a system of presumed consent for organ procurement in the near future. State bills proposing presumed consent were defeated in Maryland and Pennsylvania [8], and fear of litigation would put a serious damper on its feasibility. In 2002, however, Delaware law specified that if a person had clearly indicated his or her wish to be an organ donor the "family cannot thwart that desire after death" [17]. Kentucky, Virginia, West Virginia, Indiana, Oklahoma, South Dakota, and Tennessee have also "taken action to ensure that the expressed wishes of organ donors are carried out" [17]. Autonomy remains a priority in American medicine today along with the right of the competent patient to make all of his or her own medical decisions. Based on the proportion of people who say they are willing to donate their organs and those who actually register to do so, it seems that the organ shortage problem stems in part from a failure to obtain permission to recover organs [15]. This critical problem requires our attention.

### **References**

1. Tottoczko T. Presumed consent: what does it mean? *Transplant Proc* 2003;35:1195-1197.
2. Lopez-Navidad A, Caballero F. For a rational approach to the critical points of the cadaveric donation process. *Transplant Proc* 2001;33:795-805.
3. Gundle K. Presumed consent: an international comparison and possibilities for change in the United States. *Camb Q Healthc Ethics*. 2005;14:113-118.
4. Morris ED. The organ trail: express versus presumed consent as paths to blaze in solving a critical shortage. *Spec Law Dig Health Care Law*. 2003;295:9-34.
5. Roels L, Deschoolmeester G, Vanrenterghem Y. A profile of people objecting to organ donation in a country with a presumed consent law: data from the Belgian National Registry. *Transplant Proc* 1997;29:1473-1475.
6. Michielsen P. Presumed consent to organ donation: 10 years' experience in Belgium. *J R Soc Med*. 1996;89:663-666.
7. Kennedy I, Sells RA, Daar AS, et al. The case for "presumed consent" in organ

- donation. *Lancet* 1998;351:1650-1652.
8. Veatch RM, Pitt JB. The myth of presumed consent: ethical problems in new organ procurement strategies. *Transplant Proc* 1995;27:1888-1892.
  9. Iyer TKK. Kidneys for transplant—"opting out" law in Singapore. *Forensic Sci Int* 1987;35:131-140.
  10. Gallup poll. Majority of Americans support organ donations. 1993. Available at: [www.transweb.org/reference/articles/gallup\\_survey/gallup\\_index.html](http://www.transweb.org/reference/articles/gallup_survey/gallup_index.html). Accessed August 29, 2005.
  11. English V, Sommerville A. Presumed consent for transplantation: a dead issue after Alder Hey? *J Med Ethics*. 2003;29:147-152.
  12. Gill MB. Presumed consent, autonomy, and organ donation. *J Med Philos*. 2004;29:37-59.
  13. AMA Council on Ethical and Judicial Affairs. Strategies for cadaveric organ procurement: mandated choice and presumed consent. *JAMA*. 1994;272:809-812.
  14. Dennis JM, Hanson P, Hodge EE, Krom R, Veatch RM. An evaluation of the ethics of presumed consent and a proposal based on required response. *UNOS Update*. 1994;10:16-21.
  15. Futterman LG. Presumed consent: the solution to the critical donor shortage? The Ethics of Organ Transplant. In: Caplan AL, Coelho DH, eds. *The Ethics of Organ Transplant: The Current Debate*. Amherst, New York: Prometheus Books; 1998:161-172.
  16. Watson MB. Presumed consent for organ transplantation: a better system. *Curr Surg* 2003;60:156-157.
  17. National Conference of State Legislatures. Improved organ donor laws desperately needed. *State Legislatures*; 2002;28:7.

*Sheldon Zink, PhD, is the director of the Program for Transplant Policy and Ethics and is a senior fellow at the Center for Bioethics at the University of Pennsylvania.*

*Rachel Zeelandelaar is a recent graduate of the University of Pennsylvania and a research assistant at the Center for Bioethics. She will be attending law school starting in the fall of 2005.*

*Stacey Wertlieb, MBe, is the research manager for the Program for Transplant Policy and Ethics at the Center for Bioethics in the University of Pennsylvania.*

*The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.*

Copyright 2005 American Medical Association. All rights reserved.