

Presumed Consent: An International Comparison and Possibilities for Change in the United States

KENNETH GUNDLE

Introduction

Every day in the United States 17 people die waiting for an organ transplant. The waiting list for organs, which now contains the names of 82,000 people, has more than tripled in the last 10 years. The U.S. policy on who can donate an organ is based both on previous consent of the potential donor and on the consent of the donor's family. This foundation greatly limits the number of potential donors. Spain is the world's leader in providing organs to its population, and the underlying principle of their policy on donors in presumed consent. That is, those people who have not expressly opposed donating their organs are considered eligible for donation. This policy, along with a plan of public education and a strong infrastructure for organ procurement, is what has enhanced their donor rates. Spain is not alone: other countries have seen the benefits of presumed consent and the limits of opt-in systems. The United States must put to use the experiences of these countries to stem the tide of organ shortage and give new life to those desperately awaiting organs.

I would like to thank Dr. Philip Lee, Geoffrey Heller, and Dr. Linda Hogle for their invaluable advice on this article.

Condition in Spain and other Presumed Consent Countries:

To understand the shortcomings of the U.S. system of organ donation, comparisons to contrasting models in other countries is beneficial. In 1999 Spain had an organ donation rate of 33.6 organ donors per million people, which constituted a 142% increase in only 10 years. The United States had 21.8 per million people in the same year. In fact, Spain is the only country with over 40 million people to sustain a progressive increase in the cadaveric organ donation rate in the 1990s.

The law on which Spain's system is still founded was passed by its Parliament in 1979. For an organ donation to occur, the first requirement was a certification of brain death. "Brain death is defined as 'the total and irreversible loss of brain function' and must be certified by three doctors unrelated to the transplant teams."¹ However, unlike in the United States, a donor need not have previously and specifically self-identified as being willing to donate.

Spanish legislation, based on presumed consent, establishes that all Spanish citizens who while living do not declare their opposition to organ and tissue donation will be donors on dying if they are valid as such.²

People who register as being opposed to donation would then be ineligible. The “null” value was swapped, but an individual’s choice was never removed from the system. The added responsibility of having a specific stance falls on those unwilling to give their organs to another upon their death.

Although Spain operates under presumed consent, permission for donation is obtained from the family of the deceased. In the United States family permission is not legally required but is almost always obtained mostly due to doctors’ fears of litigation. Yet in spite of this requirement donation rates in Spain have continued to rise.

The history of Spanish organ donation can explain how the system has functioned, and why. Following the passage of the presumed consent law, a progressive increase in the number of cadaveric organs transplanted was seen up into the late 1980s. A peak was seen in 1986, when 1,182 kidney grafts were done in that single year. However, after 1986 the numbers fell somewhat, and then hit a plateau, leading to longer waiting lists. It was at that time that a critical turning point was reached: the 1989 formation of the National Transplant Organization (ONT). This led to a three-tiered system of national, regional, and local hospital management structure, where decentralization allows the hospital officials to have responsibility for decisions. “In 1989, there were scarcely 25 transplant coordinating teams in Spain, but now [in 1999] 139 teams are active, one in each hospital with the potential for organ donations.”³

This program set out to accomplish many of the same goals found in the United States. For example, the ONT itself took a special responsibility in providing education to the media and the public, “with development of educational programmes specifically designed to offer the transplant coordi-

nators the best strategies for transmitting messages to media professionals.”⁴ Other programs for education have also been present, including a training course on donation and transplantation for high school students.

This effort to reorganize the Spanish model bore great dividends. In 1989 there were 14 donors per million people, and by 1999 the number had continually grown up to 33.6 donors per million—the highest in the world. This success has benefits beyond shortened waiting lists and increased quality of life. Spain estimates that its 10,000 renal transplant recipients save approximately \$207,000,000 every year. “In Spain, transplanting a single kidney represents a savings of more than 200,000 euros in relation to the alternative of maintaining the patient on dialysis.”⁵

Spain’s system has shown itself to be a success, and presumed consent is not the sole cause. As noted above, education and media promotion, along with the ONT’s strong infrastructure, had much to do with the success of the system. What Spain did was match solid infrastructure and education to a foundation of available organs in the population as a whole. Presumed consent is the backbone of the system, but it alone does not contain the entire solution.

Is the success of Spain’s organ donation policy an anomaly? Could it be that something in their culture is the real source of success? Certainly culture does play a role in defining how a society will respond to the issue of organ donation. Research in the United States about acceptance and political feasibility of presumed consent is necessary. If Spain were the exception, then one would predict that other countries with presumed consent would not share their success; however, this is not the case.

Until 1986 Belgium did not have a presumed consent law, and although

organ transplantation began early in that country, organ shortage was a serious problem. "Major efforts had been made to increase the number of donors by sensitizing the media and informing the public and the medical profession. However, the number of donors increased only slowly."⁶ The issue of changing the Belgium law was hotly contested, but after the bill passed never more than 2% of the population has registered an objection to organ donation. In 1985 Belgium had 20 kidneys donated per million, but by only 1988 the number had risen to 37.4 per million—a very dramatic rise in a few years under presumed consent.

Was the increase in donation in Belgium due to the change in legislative framework or simply the increased publicity regarding organ donation that accompanied the legislative debate? Two similar transplant centers in Belgium, in Antwerp and Leuven, make for a good comparison. Antwerp did not switch to presumed consent following the passage of the law whereas Leuven did. Over a three-year period Leuven saw its donor rate climb from 15 to 40 donors per year, whereas Antwerp only maintained its previous levels.

Another comparison could be made between Belgium and the nearby Netherlands. Whereas in 1986 Belgium chose presumed consent, The Netherlands continued with expressed consent. Both countries started doing transplants early, have a high population density, and operate a large number of hospitals with functioning ICUs. But between 1993 and 1995 Belgium had 39.9 kidney donors per million people, whereas The Netherlands has only 27.9 per million, a trend that is similar in other organs as well.

Other countries continue this pattern of differences between opt-out and opt-in systems. In Austria presumed consent was first introduced in 1982

and the rates of donation quadrupled by 1990. The case there has been so dramatic that in 1990 the number of patients on the kidney waiting list nearly equaled the number of kidney transplants performed. And Denmark, which switched from presumed consent to expressed consent in 1986, saw its previously high donation rates fall by half.

A recent study sought to determine predictors of cadaveric organ donation in Europe. Even though the study excluded Spain due to its "extreme outlier status" its conclusions "clearly suggest that the practice of presumed consent (opting-out) legislation has had a significant effect on the number of cadaveric donors per million population."⁷ This statistical analysis succinctly shows that policy can make a significant impact, and that presumed consent results in greater numbers of organs procured.

Occasionally a critique will cite that higher than average traffic accidents in countries like Spain, Austria, and Belgium are the real contributing factor to higher donation rates simply because more people die on the road and their organs are used for transplantation. The evidence, however, does not support this. During the periods in which both Spain and Belgium's donation rates grew most rapidly, both countries saw steady declines in their rates of roadway accidents. In Austria only 30% of all organ donors come from road victims, so that this alone cannot explain the higher donation rates.

Problems in the United States

It is commonly thought that increasing the number of people with donor cards will alleviate the organ shortage in the United States. "Unfortunately, organ donor cards have not had a substantial effect on increasing the sup-

ply of organs and tissues available for transplantation."⁸ The Federal Patient Self-Determination Act of 1991 (PSDA) amended the Federal Medicare and Medicaid statutes, and as part of that act "advance directives" were emphasized as legal documents, which must be upheld by the doctor and hospital. A donor card meets all legal requirements of an advance directive, yet health providers are reticent to rely on just a donor card, and "many requestors have set a de facto precedent of seeking consent from families before donation takes place."⁹ Some of this may trace back to before the PSDA, when family consent was required as part of the Omnibus Reconciliation Act of 1986. Questionnaire results often indicate that unease about litigation is also one common reason for ignoring any valid donor document. Despite precedence for the use of organ donor cards it is the potential donor's family that can prevent transplantation from ever happening.

The work done to maximize the efficiency of the organ donation system in the United States and the attempts to raise levels of people who sign up to donate on donor cards is very commendable. Yet in 2001 6,439 people died while waiting for a transplant, up from 4,855 patients in 1998 and nearly double the 3,916 candidates who died while waiting just five years earlier in 1996. As of July 2003 over 82,000 people in the United States are awaiting the transplant of some organ, even though a waiting list of 23,000 in June of 1991 was considered a grave concern. None of these numbers show the least sign of decrease—instead there is only a steady worsening of America's organ shortage crisis.

A contributing factor in these deaths is an inability to convert available organs into successful transplants. Whereas the demand for organs has been risen 400% over the past 10 years,

the supply of cadaveric organs has remained relatively stagnant. While the waiting list has risen by 60,000, the number of deceased donors has gone up by less than 1,700—from 4,509 in 1990 to 6,182 in 2002. The technology for successful transplantation exists, and the United States has knowledgeable surgeons and an infrastructure that would allow many lives to be saved if only more organs were converted from medically suitable donors to actual transplant. At some point the system that perpetuates this problem must come into question.

Some Potential Issues in Legislation

There certainly is opposition to presumed consent, with some believing that presumed consent is unethical. One objection is that presumed consent takes away individual autonomy and that people will be disenfranchised from their own bodies. However, I argue that presumed consent provides more thorough *individual* choice than under the current system. The present "encouraged volunteerism" relies more on the consent of the family than the individual. "We do not ask relatives to make decisions for adults and so there may seem something odd about asking them about donation of adult material, particularly if the prior views of the deceased are known."¹⁰ Relatives are certainly unable to change the legal will of the deceased, so it is uncertain why they are able to alter the advance directive of a donor card. Although this may be a type of familial autonomy, the *individual's* choice is subject to filial clearance.

Under presumed consent, if a person opposes organ donation and fills out a card, he or she will certainly have that wish fulfilled. This would require a national registry system, which is feasible. If the purpose of the

organ donation community is to raise donation rates, but only through ethical means, then it follows that the wishes of those opposed to donation must be protected. More so than in the current United States system, presumed consent protects the right to refuse to donate. Is this not individual autonomy?

A system of specified refusal has the advantage that it will save lives while maintaining the ability for those opposed to refuse donation. Because specified refusal would increase organs available for transplantation, the burden lies with those who oppose such action to provide proper justification to the continued suffering of those awaiting transplantation.

The term *presumed consent* poses some semantic difficulties. The word *presumed* indicates a lack of personal choice or an assumption about a decision. But nothing is particularly presumed; what has changed is the action, from acceptance to refusal. The terminology, then, should follow this change and refer to the action of opting-out. I argue that a more appropriate designation would be *specified refusal*. This rightly refers to the person's action—that of refusal—and adequately designates that this system is about choice, not assumptions.

Conclusions

A combination of specified refusal, with the proper education campaign and an infrastructure that makes efficient use of the available organs, is the best strategy for curing an organ shortage. The United States already has in place a system of organ procurement organizations. In addition, educational campaigns are already well on their way, though more work could be done in this area. Under our current legislation little more could be done to significantly impact the rapidly increasing

waiting lists—a change in the program's foundation is required. Spain succeeded through the development of the ONT, but that organization was able to thrive with a foundation of presumed consent. In contrast, the United States has built its procurement system on top of de facto precedent and familial consent. It is time for a system of specified refusal to be pressed forward before unethical alternatives arise due to overwhelming demand.

The possibility of passing legislation changing the U.S. policy is a more complicated issue. If legislation is to move forward, more research should be done to assess the current knowledge and opinions regarding organ donation policy and specified refusal in the transplant community and on Capitol Hill. More in-depth, qualitative interviews may be more useful than surveys, especially to examine attitudes toward *presumed consent* as a term. Such knowledge would allow better informed policy to be developed with a maximum probability of success. There is also the option of trying to pass specified refusal legislation in several states as a preemptive measure to an eventual nationwide policy. This could prove the efficacy of specified refusal and provide an organizational framework for the national system.

Notes

1. Miranda B, Fernánde Lucas M, de Felipe C, Naya M, González-Posada J, Matesanz R. Organ donation in Spain. *Nephrology Dialysis Transplantation* 1999;14(Suppl. 3):15–21, at 15.
2. López-Navidad A, Caballero F, Cortés U, Martínez J, Solá R. Training course on donation and transplantation for 16- to 18-year-old schoolchildren in the Hospital de Sant Pau. *Transplantation Proceedings* 2002;34:29–34, at 29.
3. See note 1, Miranda et al. 1999:15.

Perspectives

4. See note 1, Miranda et al. 1999:16.
5. See note 2, López-Navidad et al. 2002:29.
6. Michielsen P. Presumed consent to organ donation: 10 years' experience in Belgium. *Journal of the Royal Society of Medicine* 1996;89(12):663-6.
7. Gimbel RW, Strosberg MA, Lehrman SE, Gefenas E, Taft F. Presumed consent and other predictors of cadaveric organ donation in Europe. *Progress in Transplantation* 2003;13(1):17-23.
8. The Lewin Group, Inc. (for the Office of the Assistant Secretary for Planning and Evaluation). Published January 4, 2000. Analysis of state actions regarding donor registries (25 July 2003). Available at <http://www.organdonor.gov/aspehealth.html>.
9. See note 8, The Lewin Group 2000.
10. English V, Sommerville A. Presumed consent for transplantation: A dead issue after Alder Hey? *Journal of Medical Ethics* 2003; 29:147-52.