



KEVIN CURTIS/SPL

Presumed consent is unnecessary

Spain has the highest rate of organ donation in the world, but its presumed consent legislation is dormant, say **John Fabre and colleagues**

Spain has by far the world's highest rate of organ donation from deceased donors (approximately 34-35 per million of population), which is more than twice that of the UK (approximately 15 per million of population).¹ The vast majority of Spain's deceased donors are heart beating donors diagnosed as brain stem dead in intensive care units (32 per million of population). Spain has a low rate for both live organ donation (five per million of population) and for non heart beating donation (also known as donation after cardiac death, or DCD) (2.3 per million of population, entirely from patients in whom cardiac arrest occurs unexpectedly outside hospital or in emergency departments).^{1,2} In contrast with Spain's figures, donation after cardiac death has increased steadily in the UK, and in 2009 it comprised almost a third of deceased donors (4.7 per million of population, almost entirely from patients with anticipated cardiac arrest after withdrawal of cardiorespiratory support, usually in intensive care units).

Heart beating donation in the UK has continuously fallen over the past decade, from 744 donors in 2000 (12.7 per million of population) to 612 in 2009 (10.3 per million of population). In contrast, live organ donation has almost trebled over that time, to 961 in 2009 (15.8 per million of population)—more than the number of deceased donors.³ Thus, in the UK, both the number of donors and the pattern of donation are different from those in Spain (table). Donation after cardiac death provides no hearts and few lungs for transplantation, and consequently the number of heart transplants in the UK has been falling for several years.

Spain and presumed consent

Spain introduced presumed consent legislation for organ donation in 1979, and the Spanish system is therefore universally described as an "opt-out" system. This single aspect of Spain's complex organ donation organisation has been

used as a key descriptive term, and every nation's organ donation system is described as "opt-in" or "opt-out." As a consequence, many calls have been made for the introduction of presumed consent legislation in the UK,^{4,5} on the assumption that this approach will increase rates of organ donation.

In 1980 a royal decree clarified several issues regarding Spanish citizens who did not wish to become organ donors, and is crucial to understanding the situation in Spain. The decree stated that opposition to organ donation could be expressed in any way, without formal procedures. The Spanish legal system's interpretation of this decree was that the best way to establish the potential donor's wishes was by asking the family. That is why Spanish law is a theoretical presumed consent, but in practice the system is "opt-in." The family is always asked for consent, and the family's wishes are always final.

Crucially, Spain does not have an opt-out register for those who do not wish to become organ donors. Not a penny is spent on recording objections to organ donation by Spanish citizens, nor on public awareness of the 1979 legislation. Clearly, the presumed consent law in Spain is dormant, and it pre-dates key policy changes made in 1989, described below. In these circumstances, Spain's outstanding deceased organ donor rate cannot reasonably be attributed to its presumed consent laws.

Patterns of organ donation in the UK and Spain (per million of population per year for 2009)

	Heart beating donors	Non-heart beating donors		
		DCD I and II*	DCD III*	Live donors
UK	10.3	<0.5	4.7	15.8
Spain	32	2.3	0	5

* DCD I and II refer to donation after cardiac death where cardiac arrest occurs outside the hospital or in the emergency department, whereas with DCD III cardiac arrest occurs after withdrawal of cardiorespiratory support, usually in the intensive care unit.

A positive attitude to organ donation on the part of those approaching families of potential donors is frequently claimed as a major benefit of presumed consent legislation,⁵ but it is easily possible without such legislation. This situation has been described in the United States,⁶ which has an excellent deceased donor rate of greater than 25 per million population without presumed consent laws.

Presumed consent and actual consent

The appeal of presumed consent legislation is based on the belief that if consent is a problem, presuming it will solve the problem. The misconception underlying this belief is that presumed consent equates with organ donation. In fact, presumed consent equates simply with the presumed consent of the potential donor—the actual decision to donate rests with the potential donor's family. The family bases its decision on many factors, such as trust in the medical profession, understanding of the organ donation process, the professionalism of the approach for donation, and, most importantly, the expressed wishes of the potential donor (for example, through donor register, donor card, or conversations).

Improving the consent rate

The rate of organ donation and the refusal rate in Spain from 1979 to 1989 did not change remarkably by comparison with those of other European countries. In 1989, the donation rates in Spain and the UK were approximately the same (about 14 per million population) and the refusal rates were similar (about 30-40%). In 1989 Spain introduced a comprehensive, nationally organised organ donation system that included many innovations. Over the past 20 years organ donation in Spain has risen gradually to its current enviable levels. The refusal rate has also fallen gradually to about 15%.^{1,7} In the UK, in contrast, the refusal rate has remained

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- ▶ Head to head: Is presumed consent the answer to organ shortages? (*BMJ* 2007;334:1088)
- ▶ Editorial: Presumed consent for organ donation (*BMJ* 2008;336:230)
- ▶ Research: Impact of presumed consent for organ donation on donation rates: a systematic review (*BMJ* 2009;338:a3162)

around 40% over this period and the deceased organ donation rate has changed hardly at all.

What is the difference? Over the past 20 years the UK has embarked on initiatives that, while laudable, were unlikely to solve the organ donation problem—for example, the organ donor register. The register is an excellent idea: it maintains transplantation in the public consciousness and it facilitates organ donation when potential donors are on the register. However, to imagine that the majority of the population will sign up is unrealistic. It is in any case not essential—Spain does not have a donor register. Nor indeed does the Spanish organ donation organisation actively promote donor cards, which currently cover only 8% of the population.

If the UK were overnight to reduce its refusal rate to the Spanish level of 15%, the donation rate would be about 18 or 19 per million population, half that in Spain. Clearly, major factors other than consent are shaping the rates of donation in the two countries.

Number of potential donors

A key statistic is the actual number of potential donors. The UK audit of potential donors over 2007 to 2009 identified 1150 brain stem dead patients without absolute contraindications for donation per year in intensive care units—excluding cardiothoracic intensive care units and patients older than 75 years.⁸ This number represents about 19 per million of population. If correct, it suggests that the theoretical upper limit for heart beating donations is far lower than that in Spain with current facilities and clinical practices.

A British Transplantation Society working party suggested in the mid-1990s that a potentially important difference between the UK and many European countries, including Spain, was the relatively low provision of intensive care facilities.⁹ Current figures—excluding intensive care beds associated with coronary care, neonatal, and burns units—are around 27 intensive care beds per million of population in the UK, and 87.5 beds per million of population in Spain. The figure for the UK might in practice be marginally higher because of the flexible use of high dependency unit beds. However, a major difference clearly exists between the two countries, and this could influence admissions to intensive care units. Intensive care doctors with low bed capacity might not admit patients with a poor prognosis—those most likely to become organ donors—to avoid blocking beds for patients more likely to benefit from intensive care.

Differences in end of life care practices might also be a factor. The absence of donation after withdrawal of cardiorespiratory support (DCD III) in Spain is informative (table). Intensive care doctors in the UK seem more likely to withdraw life support before brain stem death, presumably because life support is regarded as unlikely to benefit the patient. However, a broader consideration of the patient's best interests to include their wishes regarding organ donation is worthy of attention in this context.¹⁰

A simultaneous, prospective audit of potential donors in Spain and the UK, using identical criteria, would probably be valuable. It would highlight differences in provision of intensive care, intensive care admission policies, and end of life care practices as possible factors contributing to the UK's relatively poor performance.

Special characteristics of the Spanish system

The placement of transplant coordinators at each procurement hospital is a key element of the Spanish system, initiated in 1989. Additionally, transplant coordinators in Spain have a unique profile that facilitates early identification of potential donors, particularly from small hospitals. Most transplant coordinators are intensive care physicians who are dedicated only part time to organ donation activities. Transplant coordinators can therefore be appointed even at hospitals with a potentially low rate of deceased donors, and their daily work is carried out where most donors are likely to be found—in the intensive care unit.

Transplant coordinators typically spend 10-50% of their time on coordination activities, depending on the size of their hospital and its potential for organ donation. They play an active part in coordinating all aspects of the organ donation process; in particular, approaching the potential donor's family. Every day they check for potential donors in and outside of the intensive care unit. Transplant coordinators are part of the in-house staff of the hospital, appointed by and responsible to the medical director. They are not part of the transplant team. There are no specific financial incentives to identify potential donors or to increase the donor rate from their hospital, other than the additional salary received for the extra work of coordination, which depends on the size and activity of the hospital.

Training, organised nationally by the Organización Nacional de Trasplantes, is an essential component of the model. Regular courses on the entire process and on particular aspects of deceased donation have been targeted at all professionals

directly or indirectly involved in organ donation. Since 1991, more than 11 000 professionals in Spain have been trained through these courses.

Constructing a positive social climate for donation and generating trust in the donation system is a crucial objective that is achieved by close work with the media. The communications policy of the Organización Nacional de Trasplantes involves four basic principles: (1) a 24 hour telephone available for consultation with press, public, or professionals; (2) easy access at all times to the media; (3) links with journalists built through dedicated meetings to learn about mutual needs; (4) transmission of messages without intermediaries.

The importance of the family

Death is not an isolated personal event, but a profound family matter. The primacy of the family's wishes must be accepted, as it is in Spain, otherwise trust in the organ donation process could be greatly undermined. Trust is a crucial issue because of the unique circumstances surrounding deceased organ donation.

The potential donor's death is defined not by conventional criteria (the cold, blue, and stiff definition of death) but by a set of clinical criteria that establish that the brain stem is not functioning. The patient is warm and pink, and appears to be breathing normally, although breathing is performed by a ventilator. A high level of trust is needed for the family to accept that the patient really is dead. The situation frequently gives rise to irrational fears that doctors will undertreat or withhold treatment to ensure that the patient does become an organ donor.

If these fears are ignored, trust in the donation process can suffer. For example, in February 1997 Brazil introduced a "hard" form of presumed consent that did not require consent of the family. In response to widespread public and medical disquiet, the legislation was amended to make consultation with the family mandatory, but by then the damage had been done and the legislation was entirely revoked in October 1998.¹¹

Conclusions of the UK Organ Donation Taskforce

The UK Organ Donation Taskforce conducted an extensive assessment of presumed consent and concluded that this approach was unlikely to improve organ donation rates in the UK.¹² Moreover, it suggested that the costs of implementing presumed consent—approximately £45m (€53; \$70m) in establishment costs, and several million pounds per annum thereafter—

might divert resources away from more effective initiatives.¹²

Conclusions

Advocates of presumed consent often cite the Spanish organ donation system as an example of the success of presumed consent legislation. In fact, what Spain has shown is that the highest levels of organ donation can be obtained while respecting the autonomy of the individual and family, and without presumed consent.

John Fabre professor, Department of Hepatology and Transplantation, James Black Centre, King's College London School of Medicine, London SE5 9NU, UK

Paul Murphy consultant, Neuroanaesthesia and Critical Care, Leeds General Infirmary, Leeds, UK

Rafael Matesanz director, Organización Nacional de Trasplantes, Ministry of Health and Social Policy, Madrid, Spain

Correspondence to: J Fabre john.fabre@kcl.ac.uk

Accepted: 5 September 2010

Contributors: John Fabre is a past president of the British Transplantation Society (BTS) (1992-1995) and chaired a BTS Working Party on Organ Donation in the mid-1990s.⁹ He is a clinical academic with a lifetime interest in transplantation. Paul Murphy is an intensive care clinician with a major interest in donation and transplantation. He is a member of the UK Department of Health's Organ Donation Taskforce, and the National Clinical Lead for Organ Donation in the NHS Blood and Transplant Special Health Authority. Rafael Matesanz is the Director of the Organización Nacional de Trasplantes, which oversees all aspects of Spain's organ donation system, and he has played a major role in the organisation since it was founded in 1989. He has been president of the Transplant Experts Committee of the Council of Europe for seven years, president of the Public Health Committee of the European Union Council which elaborated the EU Directive of Organ Transplantation, and is an advisor to WHO for a global strategy for transplantation. All authors contributed to this article, for which John Fabre is the guarantor.

Competing interests: None declared.

Provenance and peer review: Not commissioned, externally peer reviewed.

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Cite this as: *BMJ* 2010;341:c4973

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BMJ BLOGS **Anna Dixon**

The NHS white paper—what do doctors think of their new roles?

Anna Dixon, the director of policy at the King's Fund, blogs about the government's new policy on healthcare, and what doctors think about it.

"The past few months have been busy for anyone like me whose job it is to make sense of the government's policy on healthcare. Back in August the coalition government launched a series of detailed consultations to accompany the health white paper *Equity and Excellence: Liberating the NHS*, and the 12 week period for consultation has now closed.

"Initial reactions to the white paper were broadly positive. While voicing our concern about the abolition of primary care trusts and the transfer of commissioning to general practitioners within a fairly short timescale, we and many others welcomed the idea at the heart of the government's proposal to put clinicians in charge. Given the proposed reduction in management roles, clinicians will be vital to successfully implementing the reforms.

"A look at the consultation responses from the main professional bodies suggests the government has yet to get clinicians fully on board. The British Medical Association and the Royal College of Nursing have both emphasised the risks involved in the reforms. They give some backing to the proposals, mostly centred on supporting the idea of empowering patients and clinicians, but they

each temper this with a list of risks. Even the Royal College of General Practitioners, which is generally more positive on the reforms, qualifies its support for greater GP leadership and influence with the warning that training, time, and resources are necessary to make it a success.

"We wanted to find out more about the views of front line clinicians, so we teamed up with Doctors.net.uk to survey 1000 of their members. The majority of doctors who responded to the survey did not believe that the reforms would empower patients and doctors—a goal that all the professional organisations expressed support for in their responses.

"Half of the doctors we surveyed were concerned that the NHS would not be able to maintain its focus on increasing efficiency while implementing the reforms—a key risk identified during the consultation. Doctors identified a number of factors that they believed would help meet the productivity challenge, including greater collaboration across health services and professions.

"Unless doctors and other front line workers are brought on board and develop a clear understanding of how the reforms can improve patient care, it is difficult to see how they will deliver against their objectives."

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Online journal club: should we encourage people with osteoarthritis to try glucosamine?



A debate on doc2doc, BMJ Group's global online clinical community, discusses a *BMJ* meta-analysis on the effects of glucosamine, chondroitin, or placebo in patients with osteoarthritis of hip or knee (*BMJ* 2010;341:c4675).

Richard Lehman: "If patients get any benefit, placebo or otherwise, we may be able to spare them an early death from the adverse effects of non-steroidal anti-inflammatory drugs."

Tauseef Mehrali: "I always thought that if glucosamine sulphate was going to work, it would have more chance of doing so with knee pain rather than hip pain."

Dr TS: "The harm glucosamine does is that it costs money, but the good it does is that it gives some hope. I don't know if I would tell my mother to stop taking it."

Yoram Chaiter: "When you design a double blind randomised controlled trial, you have a huge problem. That is, you give a potent agent to one group and a placebo to the other group. We are all familiar with the placebo effect. Some works claim to see up to 30% change because someone has swallowed something, due to recruitment of the immune system, or because of neurotransmitters changing."

Houckster: "I do not know how an oral preparation of cattle cartilage and shrimp shells could get to a joint to repair it other than by increasing substrate."

📖 **Do you think people with osteoarthritis should try glucosamine, or should they steer clear? Have your say at <http://bit.ly/90jBou>**