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The organs crisis and the Spanish model: theoretical versus pragmatic considerations

Muireann Quigley,[1] Margaret Brazier,[1] Ruth Chadwick,[2] Monica Navarro Michel,[3] David Paredes[4]

In the United Kingdom, the debate about how best to meet the shortfall of organs for transplantation has persisted on and off for many years. It is often presumed that the answer is simply to alter the law to a system of presumed consent. Acting perhaps on that presumption in his annual report launched in July, the Chief Medical Officer, Sir Liam Donaldson, advocated a system of organ donation based on presumed consent, the so-called "opt-out" system.[1] He is calling for a change in the law in England and Wales whereby consent to organ donation is presumed, making a person's organs automatically available for transplantation after death, unless they registered objections to this while alive. Subsequently, the British Medical Association (BMA) lent its support to the introduction of such a system.[2] The BMA contends that "the practice of presumed consent legislation has had a significant effect on the number of cadaveric donors per million population."[2]

It is often taken for granted that there must be a correlation between the enactment of legislation on presumed consent and an increase in organ donation and procurement. However, the correlation is not as straightforward as it might seem. It may be that other practical measures to encourage organ donation could be implemented without changing the Human Tissue Act 2004, an Act which has been in force for barely a year.

An analysis by Abadie and Gay demonstrated that "presumed consent legislation has a positive and sizeable effect on organ donation rates"(p599),[3] but they themselves admitted that the correlation between rates of donation and presumed consent legislation is "not completely unequivocal"(p606).[3] It is true that among the most successful cases in procurement rates are countries with presumed consent legislation (Spain, Austria, Belgium, France and Italy). However, since some of the countries with the lowest success rates also have presumed consent legislation (such as Greece and Bulgaria), change in legislation is not an absolute guarantee of an increase in organ procurement (p607,[3] p5[4]). Unfortunately, there is no straightforward relationship between number of donations and legislative action, as there are in practice a number of other determinants. However, taking those matters into account, what Abadie and Gay do show is that if explicit consent (opt-in) countries such as the UK moved to a system of presumed consent, they would experience a 25% to 30% increase in the rate of organ donation (p610).[3] Looking at current UK figures, this would represent a maximal increase in the rate of donation from 13 per million population to 16.9 per million.[5]

Even with such an increase in donor activity, the UK would still not have a rate of donation comparable with that of some other countries (p607).[3] Spain surpasses all other countries in the success of their donation programme, with a donation rate of 33.8 per million population, nearly three times the current rate of donation in the UK (data for 2006 are available on the website of the Organización Nacional de Trasplantes; ONT).[6] Consequently, Spain seems to represent a statistical outlier to Abadie and Gay's analysis, suggesting that there may be other factors responsible for their donation rates in addition to its being a country with presumed consent. It is for this reason that it would be prudent for the UK to look to Spain in order to inform the organ donation process in general, and in considering any legislative changes in particular.

THE SPANISH MODEL

Spanish legislation introducing presumed consent for deceased organ donation dates from 1979 (Spanish Law 30/1979, 27 October, on Organ Extraction and Transplant). However, it could be argued that while this has had a positive influence on organ procurement in Spain, it cannot wholly account for the current high rate of donation. There are two reasons for this. First, notwithstanding what the law says, the families are always approached as a way of understanding the wishes of the deceased about donation, or as a way of getting permission to proceed with donation if the wishes of the deceased are unknown. Organs are not taken in Spain against the wishes of bereaved relatives. Therefore, from a practical point of view, an explicit or opting-in model continues to be applied. Second, despite legislation in 1979, the figures for donation started to improve only 10 years after the Spanish ONT was created in 1989. The ONT is a national network of specifically trained, part-time, dedicated and strongly motivated hospital physicians in direct charge of the whole process of donation. Since its formation there has been an increase from 14.3 donors per million population to 33–35 donors per million in the past few years. This impressive evolution is the result of a set of measures, mostly of an organisational nature.[7 8] These measures seem to be the only set of initiatives proven to be effective in increasing deceased donation rates in a sustained way.

The key principles of the Spanish model are set out in box 1.[9 10] Of these, the transplant co-ordination network and the profile of the transplant co-ordinator can be viewed as pivotal. The *transplant co-ordination network* is organised at hospital, regional and national levels, and consists mostly of a group of specialist physicians associated with intensive care or anaesthesiology, or nephrologists, with the collaboration of registered nurses from the same fields. The ONT oversees and supports the process at the national level. All technical decisions are taken by the ONT and then implemented by the regional offices. Additionally the regional centres offer logistic, human and resources support to smaller hospitals.

At the hospital level, at the centre of the transplant co-ordination networks are active, well-respected *transplant co-ordinators* in every transplant hospital and in all

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hospitals that are legally authorised to carry out organ and tissue procurement. The co-ordinators form the largest group within the network, and although they are not direct employees of the ONT, they closely collaborate with it. The co-ordinators are "directly involved in the process of donation, developing a proactive programme of donor detection, and taking charge of donor evaluation and maintenance, approaches to the family and the courts if needed, as well as coordination of all the process of organ procurement".[9]

Furthermore, there are three types of co-ordinator, each with a specific role. These are (1) procurement co-ordinators, involved in organ and tissue procurement; (2) sharing co-ordinators, involved in organ and tissue sharing at the regional and national levels; and clinical co-ordinators, involved in the pre- and post-transplant evaluation and care of the recipients (pp15–18).[11]

WOULD THE SPANISH MODEL WORK IN THE UK?

The success of the organ procurement programme in Spain can be seen as the gold standard, but is it achievable in the UK? A brief look at Italy can further inform us about the impact of presumed consent legislation in tandem with organisational change. Italy enacted a law on Organ and Tissue Transplant on 1 April 1999, introducing both presumed consent and an organisation similar to the Spanish ONT, with national, regional and local co-ordinators. The law applies throughout Italy, but not all regions have implemented the organisational changes. Those regions that have shown a sustained increase in deceased donor activity are the ones that have implemented changes in the infrastructure and organisation of their organ donation programmes. In Tuscany, the rate of deceased donations doubled in just one year,[12] and that region saw an overall increase from a rate of 10 donors per million in 1997 to over 40 per million in 2006. Other factors may be equally important, such as the age distribution of the population, causes of death in the population, number of doctors per million and the number of acute beds and ICU facilities available.[10] But the experience in Italy shows that, as organisational measures are implemented, the rates of donation increase.

Box 1: Principles of the Spanish model of organ donor recruitment

- Transplant co-ordination network
- Special profile of the three levels of transplant co-ordination
- Continuous audit on brain deaths and outcome of donation at ICUs
- Central office as a support agency
- Great effort in training
- Hospital reimbursement
- Close attention to the media

CONCLUSIONS

The United Kingdom[i] most certainly needs changes in its system of organ procurement. The low rate of donation is a testament to the fact that the current system is not working. There is no doubt that the UK could benefit from legal and organisational change. Abadie and Gay's analysis demonstrates that there will be some improvement in donation rates correlating with the legislative change itself, but the evidence from Spain has shown that other measures are needed for the organ procurement system to be maximally successful. An adequate legal framework is important but is not enough.

Policy-makers would be misguided if they are led to believe that legislation is all there is to improve success rates of organ procurement. It may be one step on the ladder, but it is not the only step, or perhaps even the most important one. Any commitment to legislative change must be accompanied by an equally strong commitment to ensuring the creation and availability of the infrastructure and resources necessary to support such a change. And some of these changes can be made without the need for another change in the law. The implementation of an effective organisational model based on the Spanish experience is entirely possible without amendment of either the Human Tissue Act 2004, which applies in England, Wales and Northern Ireland, or the Human Tissue (Scotland) Act 2006. Opposition to changes in the law, or lack of parliamentary time, is thus no excuse for failing to act now to introduce a better practical system to improve rates of organ donation.

[i] Note that the Human Tissue Act 2004 does not apply in Scotland, which has its own Human Tissue (Scotland) Act 2006. The Scottish statute is, however, also based on an explicit (opt-in) system.

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