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The Organs Crisis and the Spanish Model: Theoretical versus Pragmatic Considerations[*†]

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] That there must be a correlation between the enactment of legislation on presumed consent and an increase in organ donation and procurement is often taken for granted. However, the correlation is not as straightforward as it might seem. And 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 Guy demonstrates that "presumed consent legislation has a positive and sizeable effect on organ donation rates".(p.599)[4], but they themselves admit that the correlation between rates of donation and presumed consent legislation is "not completely unequivocal".(p.606)[4] 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.(p.5)[3](p.607)[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 Guy do show is that if explicit consent (opt-in) countries such as the UK moved to a system of presumed consent then they would experience a 25-30% increase in the rate of organ donation.(p.610)[4] Looking at current UK figures this would represent a maximal increase in the rate of donation from 12.9 per million population (pmp) to 16.77 pmp.[5]

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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.(p.607)[4] Spain surpasses all other countries in terms of 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.[6] Consequently Spain seems to represent a statistical outlier to Abadie and Guy's analysis, suggesting that there may be other factors responsible for their donation rates in addition to it being a presumed consent country. And 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.[7] 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. Firstly, 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 the permission to proceed with donation in case 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. Secondly, despite legislation in 1979, the figures for donation only started to improve ten years later after the Spanish National Transplant Organisation (ONT, Organización Nacional de Trasplantes) 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 pmp to 33-35 donors pmp in the last few years. This impressive evolution is the result of a set of measures, mostly of an organisational nature.[8] These measures seems 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 table 1.[9] Of these the transplant coordination network and the profile of the transplant coordinator can be viewed as pivotal. The *transplant coordination network* is organised at hospital, regional, and national levels, and consists mostly a group of specialist physicians related 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 the smaller hospital. At the hospital level, at the centre of the transplant coordination network, are active, well respected *Transplant Coordinators* in every transplant hospital and in all hospitals 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 ONT, they closely collaborate with ONT. The Coordinators 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 Coordinators, each with a specific role. These are (1) Procurement Coordinator involved in organ and tissue procurement; (2) Sharing Coordinator involved in organ and tissue sharing at the regional and national levels; and Clinical Coordinator involved in the pre and post-transplant evaluation and care of the recipients.(pp.15-18)[10]

Principles of the Spanish Model
1. Transplant coordination network
2. Special profile of the three levels of transplant coordination
3. Continuous audit on brain deaths and outcome of donation at ICU's
4. Central Office as a support agency
5. Great effort in training
6. Hospital reimbursement
7. Close attention to the media

Would the Spanish Model work in the United Kingdom?

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 on the impact of presumed consent legislation in tandem with organisational change. Italy enacted a law on Organ and Tissue Transplant in 1 April 1999, introducing both presumed consent and an organisation similar to the Spanish ONT, with national, regional and local coordinators. The law applies throughout Italy but not all regions have implemented the organisational changes. Those regions which have shown a sustained increase in deceased donor activity are the ones which have implemented changes in the infrastructure and organisation of their organ donation programmes. In Tuscany, deceased donation doubled its rate of donations in the course of just one year.[11] And that region has seen an

overall increase from a rate of 10 donors pmp in 1997 to rates over 40 donors pmp 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 pmp, or the number of acute beds and ICU facilities available.[12] But the experience in Italy shows that, as organisational measures are implemented, the rates of donation increase.

Conclusion

The United Kingdom[13] 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 Guy's analysis demonstrates that there will be some improvement in donation rates correlated to the legislative change in itself, but the evidence from Spain has shown that for the organ procurement system to be maximally successful, other measures are needed. 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 organ procurement success rates. It may be one step in 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 organ donation rates.

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