

A Pretence to Consent?

Wales plans to introduce an opting out scheme for organ donation

New legislation for organ donation in Wales will introduce a 'soft opt-out system' permitting doctors to remove organs and tissue from any dead patient, unless they had specifically registered a formal objection to it, or their families give consent.

Plans to introduce new legislations to increase organ donation on death in Wales are going to cost millions, be complicated to administer and are 'ethically tricky' as well as unnecessary.

The Current Situation in the UK

An explicit or informed 'opt-in' consent system operates in the UK. Individuals authorise organ removal after death by joining a national registry, the Organ Donor Register (ODR) or making their wishes known to their family. Families can also consent to donation of organs from a deceased relative, if a person has not made a known decision either way.¹

Numbers of registered donors have steadily increased under the current system, with a record number donating organs in Wales in 2010,² primarily because of the implementation of recommendations from the Organ Donation Taskforce.³

Consent is currently central to organ and tissue donation, because it is seen as the major ethical and legal justification for removing and using organs from people.

The Welsh Proposals

In the UK, as in other countries around the world, there is a shortage of organs for transplant. The Welsh Government believes that a 'soft-opt out' scheme will normalise and increase rates of organ donation.⁴ They have decided to introduce this into Wales and are carrying out a public consultation about the practicalities of implementation.⁵ Doctors will be authorised to remove organs and tissue from any patient declared dead, unless the deceased had formally registered their objection, or unless their family does so on their death.

This consultation is being presented as a fait accompli, and not as the controversial legislative change that it is. The consultation paper fails to properly examine the ethical and practical concerns generated by an opt-out system.

¹ This accounts for 67% of donors in UK.

² 83 Welsh residents donated organs in 2010. *Proposals for Legislation on Organ and Tissue Donation: A Welsh Government White Paper. 8 November 2011.*

³ In the UK, deceased organ donation has increased by 25% in 3 years through implementation of various recommendations that have transformed the infrastructure of donation. Rudge, C & Buggins, E. 27 January 2012. 'How to Increase Organ Donation: Does Opting Out Have a Role?' *Transplantation* 2012;93: 141-144. <http://bit.ly/z4Q8F0>

⁴ Their consultation suggests that rates could increase by 25%-30%.

⁵ *Proposals for Legislation on Organ and Tissue Donation: A Welsh Government White Paper. 8 November 2011.* <http://bit.ly/z34Fwx>

1. A soft-opt out system is 'ethically tricky'⁶

Organ donation is a generous gift and a striking example of the principle of putting the needs of others before one's own needs. However consent to donation should be voluntary (un-coerced), informed and autonomous.

'Soft opt-out', otherwise known as 'presumed consent' (PC), is a misnomer. **It involves neither donation nor consent by the individual.** Silence does not amount to consent.

When organ donation becomes 'presumed', it is no longer a voluntary gift, nor a 'donation'. It is about taking, not giving organs. Although it is argued that the family would be asked for consent, this raises questions as whether it can be ethical for 'family' to consent for an individual who has not actively consented, and could have done so? And who in effect 'owns' the body after death? the State? The 'family'? or no-one?

Importantly, a system that relies on presumed authority, based solely on people registering their decision to opt out, has to ensure that everyone is informed and understanding of the situation, knows their options and can easily and simply opt out.⁷ Otherwise it cannot be ensured, in practice, that every removal of human organs is appropriately authorised, even by the family.

The Bristol and Alder Hey Inquiries showed how crucially important the body is to bereaved parents and friends. They illustrated the need to respect the human body, even in death, and not cause unnecessary distress to the mourners. Concerns about the body effectively belonging to the state at death must be heeded, along with the loss of the concept of organs being altruistic 'gifts' (recipients also stress the importance of knowing organs are freely given⁸), and controversies with the definition of death.

The state-authorized removal of the organs of a deceased person for a stranger could rarely, if at all, be in the best interests of a deceased person. However it is argued that if an opt-out system increases the number of organs available for transplant, and benefits other patients, this would be sufficient ethical justification in favour of change, so long as improvement could not be achieved by other means.

2. A soft-opt out scheme is Unnecessary

Despite claims to the contrary, there is no clear evidence that soft-opt out does increase organ donation rates. Substantial increases in donor numbers can be achieved within current legislative frameworks.

Spain introduced 'soft opt-out' or 'PC' legislation for organ donation in 1979 and now has the world's highest rate of donation from deceased donors, so is cited as a model for introducing such laws. Yet Spain's high deceased organ donor rate cannot reasonably be attributed to its PC laws. Instead, improvements in donor rates followed the implementation ten years later of a nationally organised organ donation system that included many innovations. A BMJ article comments:

⁶ Dorry L. Segev, Associate Professor of Surgery at Johns Hopkins University School of Medicine and author of research with transplant experts in 13 European nations with presumed consent legislation. Published online in *Transplantation*. <http://bit.ly/tD7yvjv>

⁷ Including, for example, the 'disorganised', the 'apathetic', those lacking full capacity and those changing their minds.

“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.”⁹

The same BMJ article also notes that the ‘excellent deceased donor rate in the US’ can be attributed to ‘a positive attitude to organ donation on the part of those approaching families of potential donors.’ An NHS Blood Transplant statement reports that Sweden has an opt-out law and yet has a lower donation rate than the UK.¹⁰

New research published in *Transplantation* this month found that donation rates in countries with PC laws do not differ dramatically from countries requiring explicit consent. Moreover: *“...countries with the highest rates of deceased donation have national and local initiatives, independent of PC, designed to attenuate the organ shortage.”*¹¹

The key factors influencing donor rates are: numbers of potential donors, provision of intensive care facilities, end of life care practices, use of transplant coordinators, trust in the donation system and trust in the medical profession (particularly those treating dying patients).

A BMJ review of research on ‘PC’ systems likewise concluded that various factors contribute to variation between countries: *“Presumed consent alone is unlikely to explain the variation in organ donation rates between different countries. A combination of legislation, availability of donors, transplantation system organisation and infrastructure, wealth and investment in healthcare, as well as underlying public attitudes to and awareness of organ donation and transplantation may all play a role, although their relative importance is unclear.”*¹²

3. A soft-opt out scheme could be Counter-Productive

Trust is a crucial issue because of the unique circumstances surrounding deceased organ donation. Concerns have been expressed about the potential to damage the vital trust between clinicians caring for people at the end of life (their patients) and their families, and possibly for intensive care practitioners to opt out of participation in donation programs.¹³

A 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. A deceased patient may appear to be breathing normally, even if through a ventilator, so a high level of trust is needed for the family to accept that a patient really is dead. If these fears are ignored, trust in the donation process will suffer.¹⁴

⁹ One of the BMJ authors, Prof Rafael Matesanz, is founder of the world’s most successful transplantation service in Spain. Fabre, P Murphy, R Matesanz. 2010. ‘Presumed consent: a distraction in the quest for increasing rates of organ donation’. *BMJ*. 341 doi: 10.1136/bmj.c4973 <http://bit.ly/ymzenx>

¹⁰ <http://bit.ly/n5HXw2>

¹¹ *Boyersky, B et al. 27 January 2012. Potential Limitations of Presumed Consent Legislation Transplantation 2012;93: 136–140. <http://bit.ly/xZFqfB>*

¹² *Rithalia, A et al., Impact of presumed consent for organ donation on donation rates: a systematic review, BMJ 2009;338:a3162. <http://bit.ly/xmR6uL>*

¹³ *“Some intensive care staff fear that a move to an opting-out system would make critical care more difficult and could lead to some intensive care practitioners themselves opting out of participation in donation programs. This would be disastrous for the future of organ donation, which is dependent on the active support of intensive care practitioners.” Rudge, C & Buggins, E. 27 January 2012. ‘How to Increase Organ Donation: Does Opting Out Have a Role?’ *Transplantation* 2012;93: 141–144. <http://bit.ly/z4Q8F0>*

¹⁴ *Fabre, P Murphy, R Matesanz. 2010. ‘Presumed consent: a distraction in the quest for increasing rates of organ*

Moreover, a soft opt-out system increases the burden placed on families at a time of stress. It could promote conflict between families and clinical staff, conflict that could rapidly degrade the trust that is vital to decision making.

4. A soft-opt out scheme will be Costly and Complicated

Implementing presumed consent legislation will take a large amount of time and energy with minimal payoff. Some of the complications and costs involved are:

- Difficulties in registering opt-out and complying with the ECHR¹⁵
- The need for conscience legislation to protect clinicians
- Enforcing a level of duty for clinicians to seek information about a deceased's views
- Establishing what constitutes a reasonable effort to establish a lack of objection
- Ensuring that family members correctly represent and honour the views of the deceased, not voicing their own.
- Assessing evidence from various family members in cases of disagreement
- Assessing the age at which children can be assumed to have presumed consent
- The legality of presumed consent for those who lack capacity to consent
- The legality of presumed consent when identity is unclear or there is no family.

The Welsh Government estimates set-up costs of £2.85m but fails to break these down or include on-going costs. In 2008 The Organ Donation Taskforce estimated in greater detail the costs of an opt-out system for the UK: database set-up costs (around £20m and £2m per annum in ongoing costs), IT costs (at least £10m initially and £2m per annum ongoing), communications campaign to support the opt out policy (£25m for an initial 3-year campaign (excluding on-going communication), and healthcare training would be 'several millions'.¹⁶ All this would be at the expense of other more effective measures.

Conclusion

***"Opt-out is not the magic bullet; it will not be the magic answer we have been looking for."*¹⁷**

The lesson from Spain is that it is possible to have the highest rates of organ donation without recourse to presumed consent.¹⁸ Instead of following a controversial, unnecessary and costly soft-opt out system, diverting resources away from more effective measures, substantial increases in donor numbers can, and should, continue to be achieved within current legislative frameworks in Wales. To boost organ transplants there need to be more transplant co-ordinators, intensive care beds, organ retrieval teams and improved public awareness.

There should be no pretence that consent exists when it does not.

donation'. *BMJ*. 341 doi: 10.1136/bmj.c4973. <http://bit.ly/ymzenx>

¹⁵ An online or paper-based register that people sign up to, to opt out, is unlikely to comply with the ECHR as this would end up with the state taking organs from the disorganised, regardless of that person's views.

¹⁶ The potential impact of an opt-out system for organ donation in the UK, Supplementary Report from the Organ Donation Taskforce, 2008. <http://bit.ly/gTdsu7>

¹⁷ Dorry L. Segev, Associate Professor of Surgery at Johns Hopkins University School of Medicine and author of research with transplant experts in 13 European nations with presumed consent legislation. This research found that, despite the laws, the process of organ donation in those countries does not differ dramatically from the process in countries, such as the United States, that require explicit consent. Published online in *Transplantation*. <http://bit.ly/tD7yiv>

¹⁸ Rudge, C & Buggins, E. 27 January 2012. 'How to Increase Organ Donation: Does Opting Out Have a Role?' *Transplantation* 2012;93: 141–144. <http://bit.ly/z4Q8F0>

Responding to the Welsh Government Consultation

Comments are invited from the public on the practical aspects of implementation as well as '*...additional comments and evidence on the proposal as a whole.*' This consultation offers an opportunity for anyone who holds concerns about the premise of the proposal, and its intended implementation, to respond by **31 January 2012.**¹⁹ **Comments from those living in Wales will be particularly useful.**

If a soft-opt out system of organ donation is implemented in Wales it will not only affect Wales but in the long-term will make it harder for the rest of the UK to resist similar changes.

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January 2012

¹⁹ *Proposals for Legislation on Organ and Tissue Donation: A Welsh Government White Paper. 8 November 2011.*
<http://bit.ly/z34Fwx>