

Proposed Organ and Tissue Donation (Scotland) Bill

'A proposal for a Bill to amend the law on human transplantation, including by authorising (in certain circumstances) the posthumous removal of organs and tissue from an adult who had not given express consent'

Consultation response on behalf of the Christian Medical Fellowship

The Christian Medical Fellowship (CMF) was founded in 1949 and is an interdenominational organisation with over 4,000 British doctor members in all branches of medicine and around 1,000 medical student members. We are the UK's largest faith-based group of health professionals. Of these members, we have 457 graduate and 72 student members in Scotland. A registered charity, we are linked to about 70 similar bodies in other countries throughout the world.

As an organisation representing the views of many who will be directly impacted in implementing this proposed legislation, we welcome this opportunity to highlight our concerns.

CMF is supportive of organ donation in principle. Organ donation is a generous gift and an example of altruism. We concur with the statement issued by the Bishops of the Church in Wales that Christians should be encouraged to join the donor register, but organ donation is an *'altruistic gift'* that should be *'freely given, not assumed'*.¹

CMF does not support 'presuming' consent when it has not been given, nor do we support overriding the family and the important role they should play. In summary, **CMF believes that plans to introduce new opt-out legislation for organ donation on death in Scotland will cost millions, will be highly complicated to administer, are entirely unnecessary and are ethically problematic.**

Consultation questions

- 1. The overarching purpose of my proposal is to move from the current opt-in system to a soft opt-out system of organ donation. Do you support this move? Please indicate 'yes/no/undecided' and explain the reasons for your response.**

No.

Organ donation is a generous sacrificial 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 fully voluntary (un-coerced), fully informed and autonomous.

This proposed new opt-out legislation to increase organ donation on death in Scotland is unnecessary, will cost millions, will be highly complicated to administer and is ethically problematic.

¹ <http://www.theguardian.com/society/2012/jun/18/wales-organ-donor-scheme-opt-out>

From an ethical perspective, 'soft opt-out', or 'presumed consent', is a misnomer. It involves neither donation nor consent by the individual. Silence does not amount to consent. Indeed, in opt-out countries where surveys have been conducted, they have revealed that the public is either unaware or does not understand the rationale of 'silence gives consent'.² When organ donation becomes 'presumed', it is no longer a voluntary gift, nor a 'donation'. It is about taking, not giving organs.

The Archbishop of Wales has said that: *'Giving organs is the most generous act of self-giving imaginable but it has to be a choice that is freely embraced, not something that the State assumes. Put more crudely, it turns volunteers into conscripts. Presumed consent is not really consent at all, merely the assumption that there are no objections.'*³

If a system were to be put into place in which there is any uncertainty about the expressed wishes of the deceased person and body parts are removed, then the procedure would be ethically unacceptable. An opt-out system cannot guarantee that the very important informed explicit consent principle is always respected.

A system that relies on 'presumed' authority, based solely on people actively 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. Otherwise it cannot be ensured, in practice, that every removal of human organs is appropriately authorised, even by the family.

Can consent be truly assumed from those who are disorganised, apathetic, disabled, less well educated or informed, isolated, lacking full capacity, of different languages and race, suffering from (temporary) mental illness, dependent, those who have less ready access to information and those who change their minds?

There are further ethical concerns about the body effectively belonging to the state at death, which must be heeded. Who in effect would 'own' the body after death? The State? The 'family'? or no-one? We expand further on this at Q3 below.

CMF believes that a **genuine opt-in system** should be implemented in Scotland, not an opt-out system.

- 2. How essential is it to change the law (from an opt-in to a soft opt-out system) in order to achieve the intended benefits (increased transplant rates, reduced waiting lists)? Are there other (non-legislative) measures that could achieve similar outcomes without the need for legislation?**

There are better and more effective options to pursue.

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 – and already have - within current legislative frameworks.

² In Hungary, for example, the opt-out system, has been in force since 1998. However, in 2003, only 42% of the general public knew about the legal regulation. (Cf Szanto Zs et al: LAM 2004; 14(89):620-6, cited by Aniko Smudla MD, Katalin Hegedus Ph.D., Semmelweis University, Institute of Behavioural Studies, Budapest).

³ <http://www.churchinwales.org.uk/structure/bishops/sermons/b43.php>

Research published in *Transplantation* has found that donation rates in countries with opt-out laws do **not differ dramatically** from countries requiring explicit (opt-in) consent. Moreover: ‘...countries with the highest rates of deceased donation have national and local initiatives, independent of PC, designed to attenuate the organ shortage.’⁴

The lesson from Spain and elsewhere is that it is possible to have the highest rates of organ donation **without** recourse to presumed consent.⁵ 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:

*‘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.’*⁶

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.⁷

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The key factors influencing donor rates are:

- numbers of potential donors
- provision of intensive care facilities
- end of life care practices
- use of transplant coordinator

⁴ Boyarsky B, et al. Potential Limitations of Presumed Consent Legislation. *Transplantation* 2012;93:136–140. <http://bit.ly/xZFqfB> See also: Coppen, R., Friele, R., Marquet, R. and Gevers, S. (2005). ‘Opting-out systems: no guarantee for higher donation rates.’ *Transplant International* 18: 1275-1279.

⁵ 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>

⁶ 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>

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http://www.organdonation.nhs.uk/newsroom/statements_and_stances/statements/opt_in_or_out.asp

⁸ Boyarsky, B et al. 27 January 2012. Potential Limitations of Presumed Consent Legislation *Transplantation* 2012;93: 136–140. <http://bit.ly/xZFqfB>

- trust in the donation system
- trust in the medical profession (particularly those treating dying patients).

A BMJ review of research on 'presumed consent' 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.'*⁹

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 Scotland, as the organ donation taskforce recommended in 2008.¹⁰

To boost organ transplants there needs to be more transplant co-ordinators, intensive care beds, organ retrieval teams and improved public awareness.

Moreover, it should of course be a priority before any consideration of legislation in Scotland that there has been a full assessment of the change in the Welsh legislation, particularly whether it has been effective in increasing the donation rate. It would be inappropriate to introduce a system that does not provide real advantages.

3. **I believe the role of the family should be limited to being consulted on whether they are aware of any (unregistered) objection by the deceased rather than asking for their consent. Do you agree? Please indicate 'yes/no/undecided' and explain the reasons for your response.**

No.

The family should always be consulted as they are the ones who are most likely to know the last wishes of the deceased.

CMF supports the principle that the deceased person's wishes should be respected as long as they reflect an 'informed decision', whether these have been expressed verbally or in writing (for example, using donor cards or a registration on the Organ Donor Register).¹¹ This principle implies that when the deceased's wishes are clear, the nearest relatives should **not** have a right of veto.

Under an opt-out system, the removal of organs from a deceased person should only be acceptable if the nearest relative was absolutely certain that the deceased person was

⁹ 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>

¹⁰ Potential impact of an opt-out system for organ donation in the UK, Supplementary Report from the Organ Donation Taskforce, 2008.

¹¹ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10. <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

aware of the authorisation system, had not objected to the procedure and had very recently shared his or her wishes with his or her nearest relative

However we believe the family should be permitted to give consent, or withhold it, when there is any uncertainty about the deceased's wishes. Consent underlies the relationship between a doctor and patients and their families.

Why should a family be able to veto donation?

1. Increased distress. The Bristol and Alder Hey controversies were fuelled by the perception that families had no real power in decision-making with respect to what happened to their loved ones body parts. They also showed how crucially important the body is to bereaved parents and friends, and illustrated the need to respect the human body, even in death. It is not simply raw material. At this hospital, body parts of children were retained after post-mortem examination when healthcare professionals 'presumed' that this would be acceptable to parents without consultation.

The damage done by this illustrates how crucially important the body is to bereaved parents and friends, and the need to respect the human body, even in death, and not cause unnecessary distress to the mourners who have to live with the memory for the rest of their lives.

There are occasional situations where continuing with donation will increase distress for a family at a tremendously difficult time. The decision about whether to donate has to be made quickly, and families might well find that they cannot agree to donate. If their wishes not to donate are then overridden, even if in accordance with the wish of the deceased to donate, this might well increase the distress families are already feeling.

2. Cultural sensitivity. Not all cultures are as individualistic or materialistic as the mainstream Western tradition, and in some cultures, individuals wishes do not override those of the family. In such situations it may well be culturally insensitive to insist that they do.

3. Lack of trust. Some people fear that if they became seriously ill, they would receive less thorough treatment if they were donors than if they were non-donors because doctors want their organs. This fear – which need not be well founded to have an effect – would increase if the family's views were known to be overridden. People look to their families to protect them when they cannot protect themselves. Publicly overriding families could make people and their families feel more vulnerable to doctors skimping on their treatment and so more reluctant to donate.

Moreover, some donors will only consent to donation of certain organs (there may be concerns about the possibility of brain and gonad transplantation, for example) and so will look to their families to ensure that their specific wishes are carried out.

An important article in the journal *Transplantation* warns of the potential to damage the vital trust between clinicians caring for people at the end of life (their patients) and their families, leading to intensive care practitioners opting out of participation in donation programs:

*'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.'*¹²

Trust between families and clinicians is a crucial issue because of the unique circumstances surrounding deceased organ donation. If there is a lack of trust, for any reason, it will make the whole scheme counter-productive and may actually lead to fewer donations than would have occurred under an opt-in system. Any conflict between families and clinical staff would rapidly degrade the trust that is vital to decision making.

4. Concern about consent. It will be almost impossible to guarantee that everyone is informed and understanding of 'deemed consent', knows their options and can easily opt out. Can consent be truly assumed from those who are disorganised, apathetic, disabled, less well educated or informed, isolated, lacking full capacity, of different languages and race, suffering from (temporary) mental illness, dependent, those who have less ready access to information and those who change their minds? The importance of allowing families a veto in such cases is obvious.

5. Ownership of the body. Underpinning the proposed change in the law is a change in the relationship between the individual and the state. The assumption about whose body it is begins to move from personal ownership to state ownership. Unless the state wishes to suggest that the deceased now belongs to it, the family must have the right to become his/her spokesperson.

The consultation fails to ask the central question about 'ownership' of the body on death: who in effect 'owns' the body after death? The State? The 'family'? No-one? The answer to this question will direct the response to what role the family should be given, and the State. Opt-out appears to carry the implicit assumption that the State, and not the family, 'owns' the body after death and this perception will further undermine trust.

- 4. Do you think an individual should be able to appoint a proxy to the make the final decision regarding transplantation on their behalf? Please indicate 'yes/no/undecided' and explain the reasons for your response.**

Yes. An individual should be able to appoint a proxy to make the final decision regarding transplantation on their behalf.

If there is no expression of wishes by the deceased and no close relative or proxy appointed, no organ retrieval should take place.

- 5. My proposal is that only adults should be automatically opted-in to be a donor. Younger persons would have to register to be a donor, by themselves or with parental consent as they currently do. This approach is I believe the best way to**

¹² *"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>

safeguard children and young people. Do you agree? Please indicate 'yes/no/undecided' and explain the reasons for your response.

Yes. While we strongly disagree with moving to a opt-out system, for reasons cited above, if it were to be introduced, the carrying of an organ donor card, or the registering of their names on the Organ Donor Register should be appropriate indication of the individual's wishes.

- 6. Do you agree the age limit for an adult should be set at 16 years old? Please indicate 'yes/no/undecided' and explain the reasons for your response. If you answered no, what would you consider a more appropriate age?**

N/A

- 7. Do you agree the soft opt-out system should apply to people who have been resident in Scotland for a minimum period of one year prior to their death? Please indicate 'yes/no/undecided' and explain the reasons for your response.**

We strongly disagree with moving to a opt-out system, for the reasons cited above.

We support an opt-in system, where length residency would have no impact and where a person could donate even if they have been resident in Scotland for less than a year prior to their death.

- 8. If you answered no to the above how long, if any, should this period of residency last before they become subject to the soft opt-out system? Would this residency need to be for a continuous period?**

See Q7 above

- 9. Do you think six months is a long enough period to run a campaign prior to change over?**

N/A

- 10. What is your assessment of the likely financial implications (if any) of the proposed Bill to you or your organisation? What (if any) other significant financial implications are likely to arise?**

The price to be paid for introducing this unnecessary (and unethical) legislation is unknown. The Welsh Government roughly estimated their set-up costs of £2.85m but failed to break these down or include on-going costs.

In 2008 a supplementary report by The Organ Donation Taskforce ¹³ estimated in far greater detail the costs of an opt-out system for the UK (based on costs at that time): 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

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(£25m for an initial three-year campaign (**excluding** on-going communication), and healthcare training would be 'several millions'.

All this would be at the expense of other more effective measures, and in a time of challenging economic circumstances.

Not only will plans for new legislation be costly, they will be highly complicated to administer.

11. Is the proposed Bill likely to have any substantial positive or negative implications for equality? If it is likely to have a substantial negative implication, how might this be minimised or avoided?

Yes. Even with a major - and costly - public awareness campaign, it will never be possible to guarantee that everyone is informed and understanding of the situation, knows their options and can easily and simply opt out.

The groups most likely to fail to express their views by signing up to a register, or removing their name from one, even if they hold personal views on this, will include those who are disorganised, apathetic, disabled, less well educated or informed, lacking full capacity, of different languages and race, suffering from mental illness, dependent, those who have less ready access to information and those changing their minds.

12. Do you have any other comments on or suggestions relevant to the proposal?

There will be an impact on another group of people - clinicians who have ethical reservations about participating in this process.

Under an opt-out system clinicians would play a key role in a number of decisions, such as:

- 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.
- Identifying and defining those who lack capacity.

Conscience legislation or guarantees will be essential to protect clinicians who do not wish to be part of this process, particularly where consent has not been expressly given or where the family objects.

We also anticipate that further legislation or guidance may be required to enforce a certain level of duty for clinicians to seek information about a deceased's views.

These added complications and costs simply highlight our concern that implementing opt-out legislation will take a large amount of time and energy with minimal payoff and benefit.

**Christian Medical Fellowship
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