

Draft Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill¹

Consultation response from Christian Medical Fellowship

October 2015

A Member's Bill introduced by Anne McTaggart MSP on 1 June 2015 proposes to amend the law on the removal of parts of the human body for transplantation by providing for decisions to be made on behalf of a deceased adult by a proxy and by authorising removal and use in certain cases where the deceased adult has not recorded an objection.

The Scottish Parliament has invited submission of written views to the Health and Sport Committee in relation to the inquiry remit.²

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 **454 graduate and 100 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 submit our views on the draft Bill.

We note at the outset that it should 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 Wales in increasing the donation rate. It would be inappropriate to introduce a controversial system to Scotland when there is no clear evidence that it will provide real advantages.

Do you support the Bill?

While CMF supports organ donation in principle, we cannot support this Bill.

CMF considers any 'opt-out' system for organ donation to be both ethically problematic and practically unnecessary. Instead, we support and encourage the use of 'opt-in' systems for organ donation.

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, and we fully support it. Providing organs for transplantation both saves and enhances life, yet there are not enough to supply the needs of many patients. The problem is becoming an increasing challenge for health care providers and the Government. New ways are constantly being sought to increase donor numbers, hence the drive behind this Bill.

¹ <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89893.aspx>

² <http://www.scottish.parliament.uk/parliamentarybusiness/CurrentCommittees/91948.aspx>

However consent to organ donation should be completely voluntary (un-coerced), fully informed and autonomous. **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'.³

In many ways, it is the success of transplantation surgery and advances in technology that have led to current challenges of unmet need for transplant and to waiting lists for organs. People are living longer, sometimes with multiple medical co-morbidities, which means that more people will need transplants.

But that generates another problem because while some proposals and methods of increasing donation are uncontroversial and should be welcomed others are far more ethically problematic.

Consent is our primary ethical concern here. Consent is the golden thread running through most medical procedures and also the Human Tissue Act 2004, which covers organ donation. Donation for transplantation is one of the scheduled purposes where consent is required.

The proposed system could not guarantee that the very important **informed explicit consent** principle will always be respected. If there is no direct consent required, as is proposed, 'consent' would rely upon an extensive public information programme, which would need to capture **the entire adult population including those on the margins of society** otherwise it will be almost impossible to guarantee that everyone is informed and understanding of the consent process, 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?

Any system that is put into place in which there is **any uncertainty** about the expressed wishes of the deceased person (including 'silence') and body parts are removed, then the procedure would be ethically unacceptable.

Organ donation should remain an altruistic, free gift in the context of fully informed and considered consent, which this Bill would not enable.

1. Do you think the Bill (if enacted) would achieve its aim of increasing the number of organs and tissue made available for transplantation in Scotland? Please provide an explanation for your answer.

Not only is this Bill ethically problematic, it is unnecessary. There is little evidence that it will achieve its purpose.

Substantial increases in donor numbers can be achieved – and already have been - within current legislative frameworks. The way to increase donor numbers does NOT depend upon changing the law.

³ 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).

Over the last five years the number and proportion of people in Scotland on the NHS Organ Donor Register has increased markedly – from 29% to over 41% at the end of 2012/13. Amongst the UK countries, Scotland now has the highest proportion of its population on the Register.⁴ A paper in *'Transplantation'* makes the point that in the UK, deceased organ donation has increased by 25% in three years through implementation of various recommendations that have transformed the infrastructure of donation.⁵ In other words, **not** through introducing an opt-out system. And there is no reason why this upward trend should not continue.

There is no clear evidence that 'soft' opt-out does increase organ donation rates.

Spain is often held up as a model to follow, with presumed consent legislation and high donation rates. But this should not be assumed to be a causal connection because the threefold increase in organ donation in Spain occurred **without** changing the law. Despite the enactment of an opt-out scheme in 1979, a significant transformation in the level of donations took place ten years later, only *after* investment in infrastructure in 1989.

A British Medical Journal (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.'*

And, importantly, an NHS Blood Transplant statement notes that Sweden has an opt-out law and **yet has a lower donation rate than the UK.**⁷

Donation rates are more dependent on other factors.

The Director of the Spanish National Transplant Organisation, Dr Rafael Matesanz, made it quite clear when giving evidence to the House of Lords that the key to success in Spain has been due to organisational changes, not legislation, for example, having a centralised office for coordination, regional organ donation coordinators and trained coordinators in each hospital to talk to families.⁸

⁴ A Donation and Transplantation Plan For Scotland 2013-2020,
<http://www.scotland.gov.uk/Publications/2013/07/7461/4>

⁵ http://journals.lww.com/transplantjournal/Abstract/2012/01270/How_to_Increase_Organ_Donation_Does_Opting_Out.3.aspx

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>

⁷ https://www.organdonation.nhs.uk/newsroom/statements_and_stances/statements/opt_in_or_out.asp/

⁸ <http://www.publications.parliament.uk/pa/ld200708/ldselect/ldcom/123/123i.pdf>

*'I would emphasise this point that I believe it is the structure rather than the law. Spain pro rata has three times as many intensive care beds as in this country and it has three times as many donors pro rata. Spain has three times as many organ donor co-ordinators as in this country and it has three times as many organ donors. I do not think those two things are a coincidence.'*⁹

Research published in *Transplantation* 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."*¹⁰

This reiterates again the central drivers for change in donation rates; **they are not driven by legislative change but by cultural and logistical factors**. This is simply because there are many factors, more important than legislation, that affect donor rates.

These include public awareness, religion, cultural attitudes to donation, hospital processes, provision of intensive care beds and numbers of road deaths, to name a few. In Spain, an important factor is ensuring that the relatives of potential organ donors are always approached by someone specifically trained for the purpose. In the UK one measure already introduced to increase donation rates is through the driving licence application.¹¹ Now, everyone who applies for a driving licence online has to answer questions about organ donation before being able to complete their application. The aim is to get people thinking about organ donation and increase the number of people on the organ donor register.

In fact, a move to an 'opt-out' system could prove to be counter-productive, a warning highlighted in *'Transplantation'*: *'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

This is one reason we suggest at the outset of our submission that, before any consideration of legislation in Scotland, there should be a full assessment of the change in the Welsh legislation, particularly whether it has been effective in increasing the numbers of actual organ donations or not.

2. Do you support the proposal of appointing a proxy? Please provide an explanation for your answer

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

⁹ <http://www.publications.parliament.uk/pa/ld200708/ldselect/ldcom/123/123i.pdf>

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http://journals.lww.com/transplantjournal/Abstract/2012/01270/Potential_Limitations_of_Presumed_Consent.2.aspx

¹¹ http://www.direct.gov.uk/en/N11/Newsroom/DG_198724

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http://journals.lww.com/transplantjournal/Abstract/2012/01270/How_to_Increase_Organ_Donation_Does_Opting_Out.3.aspx

We do have some reservations with this however, as, ideally, the family or an appointed proxy should always be consulted as the ones who are most likely to know the last wishes of the deceased. However it is not always possible to guarantee their capacity to make a decision that truly represents the wishes of the deceased. Proxies are often poor at substituting judgement for another and often only a random chance exists of making the same decision. We are therefore concerned about the potential for serious mistakes resulting from the possibility of a proxy or close relative authorising the removal of body parts from a deceased person who has not left any specific expression of wishes.¹³

Under an opt-out system, the removal of organs from a deceased person should **only** be acceptable if the nearest relative (or proxy) was **absolutely certain** that the deceased person was aware of the authorisation system, had not objected to the procedure and had recently shared his or her wishes with his or her nearest relative or proxy.

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 clear opt-out from the organ donation register). This principle implies that when the deceased's wishes are clear, the nearest relatives or a proxy should **not** have a right of veto.

However we believe the family should be permitted to give consent, or withhold it, when there is any uncertainty about the deceased's wishes.

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 given), and controversies with the definition of death. It cannot be 'presumed' – as was the case with these Inquiries – that body parts can be used without explicit consent.

Trust between families, proxies and clinicians is crucial 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, proxies and clinical staff would rapidly degrade the trust that is vital to decision making.

3. Do you have any comments on the role of “authorised investigating persons” as provided for in the Bill?

No comment.

4. Is there anything in the Bill you would change? If yes, please provide more details.

¹³ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 12.
<http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

If this Bill were to be passed, 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.

However CMF believes that a **genuine opt-in system** should be implemented in Scotland, not an opt-out system. As we have made clear above, an opt-out system will not be a 'magic bullet' with the outcomes that are predicted.

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 through structural changes such as more transplant co-ordinators, intensive care beds and organ retrieval teams.

**Public Policy Department
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