

**If you are a representative of a group or organisation, please tell us a little bit about that organisation or group :**

*The Christian Medical Fellowship (CMF) is an interdenominational organisation with over 4,000 British doctors and 1,000 medical students as members. We have members in all branches of the profession, and through the International Christian Medical and Dental Association are linked with like-minded colleagues in more than 90 other countries.*

*154 doctors reside in Wales and there are 63 student members at the two Welsh medical schools.*

*We run conferences and events, produce publications, coordinate local groups, support UK doctors working abroad, offer advocacy and support and provide a voice to church, profession and society on issues at the interface of Christianity and medicine. CMF regularly makes submissions on ethical and professional matters to Government committees and official bodies. All submissions are on our website ([www.cmf.org.uk/ethics/submissions/](http://www.cmf.org.uk/ethics/submissions/)).*

*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 believes that **plans to introduce new soft opt-out legislation to increase organ donation on death in Wales will cost millions, will be highly complicated to administer, are entirely unnecessary and are ethically problematic.***

*Whilst we answer the majority of the questions in the consultation paper, as requested, we set out in more detail our members views at Q9 below.*

### ***Persons who will be included in the soft opt-out system***

1. The White Paper sets out individuals must have lived in Wales for a sufficient period of time before being included within the soft opt-out system.

- . a) What factors should be taken into account when determining whether an individual ‘lives in Wales’?

*N/A Please see our response to Q9 below.*

- . b) What should that period of time be?

. *N/A Please see our response to Q9 below.*

2. Do you agree discussions between clinicians and family in the event of an individual's death, will identify and safeguard those who lack capacity?

*We disagree.*

*Please see our response to Q8 and Q9 below.*

*We are concerned about an over-reliance on the views of family as we note in more detail at Q8. There are significant complexities and costs that would be generated under a soft opt-out system in order to protect those who lack capacity from misrepresentation by family or others. There would also be a need for legislative guidance to define, identify and protect those who lack capacity and a need for conscience legislation to protect clinicians, none of which is dealt with in the consultation proposals.*

*Moreover, **the very legality of presumed consent for those who lack any capacity to consent is highly questionable.***

3. Do you agree that the soft opt-out system for Wales should only apply to persons aged 18 years and over? If not, why?

*We disagree.*

*The soft opt-out should not apply to ANY persons at all, whether over 18, or under 18 years.*

*Please see our response to Q9 below.*

### ***The operation of the soft opt-out system for Wales***

4. Do you agree with the retention of the existing Organ Donor Register to be operated in conjunction with the soft opt-out system?

*We disagree.*

*The ODR should certainly be retained and individuals encouraged to sign up to it. However **it should not operate in conjunction with a soft opt-out system, and a soft opt-out system should not be introduced.***

*Please see our response to Q9 below.*

5. In relation to the record keeping options for the soft opt-

out system –

- . a) Which of the suggested options do you prefer?  
(See paragraph 56 of the White Paper.)

*N/A Please see our response to Q9 below.*

- . b) Are there other options you feel would provide an effective and secure system?

*N/A Please see our response to Q9 below.*

6. What is the role of the family in safeguarding the wishes of the deceased?

*Families may already consent to donation of organs from a deceased relative, if a person has not made a known decision either way, under the current opt-in system of consent. This accounts for 67% of donors in the UK.*

***This role should remain as it is, operating under the current opt-in system.***

*As we highlight at Q8 and Q9 below, a soft opt-out system raises questions as to whether it can be ethical for ‘family’ to consent for an individual who has not actively consented, but who could have done so. Relying solely on family under a presumed consent system is liable to generate conflicting views and, consequently, difficulties in assessing evidence from various family members in cases of disagreement. Furthermore, it can never be always guaranteed that family members correctly represent and honour the views of the deceased, and do not voice their own views. (we note here the principle under the Mental Capacity Act 2005 that the family must convey the person’s wishes, it is not a proxy system).*

*There is no mention in the consultation of the importance of a trusting relationship between family and clinicians. Trust 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.*

*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 or over-ridden, trust in the donation process will suffer.*

*In this respect, concerns have been expressed in a recent issue of 'Transplantation' about 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.<sup>1</sup>*

*The legality of consent when identity is unclear or there is no family may be open to challenge.*

*More generally, the consultation fails to ask the important 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 that 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. The Alder Hey controversy was fuelled by the perception that families had no real power in decision-making with respect to what happened to their loved one's body parts.*

## **Implementation**

### **7. How can the Welsh Government ensure that the public awareness campaign is effective?**

*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.*

**Silence does not amount to consent.** *Therefore in such cases, soft opt-out will involve neither 'donation' nor consent by the individual.*

*We further note here that there may prove to be some difficulties in registering opt-out and complying with the European court of Human Rights (ECHR). An online or paper-based register that people sign up to, to opt-out, is unlikely to*

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<sup>1</sup> "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>

*comply with the ECHR as this would end up with the state taking organs from the disorganised, regardless of that person's views.*

*It would be less costly, more effective and more ethical to proceed with a public awareness campaign to increase numbers of individuals signing up to the ODR and prepared to donate their organs under the current opt-in system.*

**8. The Welsh Government would welcome your views on the potential impact of the proposed soft opt-out system for the Welsh Language, race, faith, disability, age, sexual orientation, gender, gender reassignment, marriage or civil partnership.**

*The impact of the soft opt-out system will be damaging to the concept of consent per se. A system that relies on presumed authority, based solely on people registering their decision to opt out, has to ensure that everyone is fully 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.*

*The groups most likely to fail to express their views, even if they hold 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. Silence in such cases would not amount to consent. Therefore, in such cases, soft opt-out will involve neither donation nor consent by the individual.*

*There is no mention in the consultation of the potential impact on another group of people - clinicians who have ethical reservations about participating in this process. Conscience legislation or guarantees will be essential to protect clinicians. Under a soft 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), and assessing evidence from various family members in cases of disagreement. Some will be required to identify and define those who lack capacity. We suspect further legislation or guidance would be required to enforce also a certain level of duty for clinicians to seek information about a deceased's views.*

*These complications and costs simply highlight our concern that implementing presumed consent legislation will take a large amount of time and energy with minimal payoff.*

**9. The Welsh Government has asked a number of specific**

questions; if you have any related issues which have not been specifically addressed, please record them here.

*It is striking and concerning that no questions in the consultation ask whether people support presumed consent/soft opt-out. 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.*

***Importantly, the proposed legislation is entirely 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:*

*"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."<sup>2</sup>*

*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.<sup>3</sup>*

*New research published in Transplantation just 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."<sup>4</sup>*

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<sup>2</sup> 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>

<sup>3</sup> <http://bit.ly/n5HXw2>

<sup>4</sup> Boyarsky, B et al. 27 January 2012. Potential Limitations of Presumed Consent Legislation *Transplantation* 2012;93: 136–140. <http://bit.ly/xZFqfB>

*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."<sup>5</sup>*

### ***The proposed legislation will cost millions.***

*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'.<sup>6</sup> All this would be at the expense of other more effective measures.*

### ***The proposed legislation is ethically problematic and highly controversial.***

*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), informed and autonomous.*

*Soft opt-out, or presumed consent, 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? Families are also likely to feel a greater sense of psychological pressure and coercion when starting from a default position where all the power in decision-making is perceived to lie not with them but with*

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<sup>5</sup> 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>

<sup>6</sup> 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>

*the state.*

*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. 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 given<sup>7</sup>), and controversies with the definition of death.*

***There are better and more effective options to pursue.***

*The lesson from Spain and elsewhere is that it is possible to have the highest rates of organ donation without recourse to presumed consent.<sup>8</sup> 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.*

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<sup>8</sup> 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>