

The Christian Medical Fellowship (CMF) is an interdenominational organisation with over 5,000 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.

452 of our members reside in Scotland and there are 93 student members at five different Scottish 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/).

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 Scotland will cost millions, will be highly complicated to administer, are entirely unnecessary and are ethically problematic.

Our main focus has rested on question 1, due to our opposition to the principle of opt-out organ donation.

Question 1 - what do you think of the principle of a soft opt out system for Scotland?

While CMF supports organ donation in principle, we cannot support an opt-out system, even if it is 'soft'. CMF considers this system to be both ethically problematic and practically unnecessary.

Organ donation as an altruistic gift is 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 those on waiting lists. 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.

Substantial increases in donor numbers can be achieved within current legislative frameworks

Despite claims to the contrary, there is no clear evidence that soft-opt out does increase organ donation rates.

There should be a full assessment of the results of the change in the Welsh legislation that was introduced on the 1st December 2015, particularly whether it has been effective in increasing the numbers of actual organ donations or not. Preliminary data suggests that there has been little

change; even a small decrease in the first 3 quarters of 2016/17.¹ Total deceased donors were 39, compared to 64 for the whole of 2014/15, and 25 living donors, compared to 30 in 2014/15, and 42 in 2012/13.² While it is too early to say if these trends are significant, it does suggest that the headlines expressing strong advances in organ donation rates in Wales may prove to be exaggerated.

As stated in the consultation document, Spain introduced 'soft opt-out' or 'Presumed Consent (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 review *Presumed consent: a distraction in the quest for increasing rates of organ donation*, 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.'³

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.' We can see this in the consultation document, where certain countries have opt-out systems, but have lower donation rates to the US or UK.

From 2007/08 to 2012/13, the number and proportion of people in Scotland on the NHS Organ Donor Register has increased markedly – from 29% to over 41%. Amongst the UK countries, Scotland had the highest proportion of its population on the Register⁴ **at the end of this period.**

Research published in Transplantation 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.'⁵

Another paper makes the point that in the UK, deceased organ donation increased by 25% in three years through implementation of various recommendations that have transformed the

¹ McCartney, M., When organ donation isn't a donation, BMJ 2017;356:j1028
http://www.bmj.com/content/356/bmj.j1028?utm_medium=email&utm_campaign_name=20170362&utm_source=etoc_weekly

² NHS Blood and Transplant. Organ donation and transplant activity Wales. Jan 2017.
<https://nhsbt.dbe.blob.core.windows.net/umbraco-assets/1518/wales.pdf>.

³ 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>

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

⁵ Boyarsky, B et al. 27 January 2012. Potential Limitations of Presumed Consent Legislation Transplantation 2012;93: 136–140. <http://bit.ly/xZFqfB>

infrastructure of donation.⁶ In other words, not through introducing an opt-out system. And there is no reason why this upward trend should not continue.

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). They also 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 the UK one measure already introduced to increase donation rates is through the driving licence application. 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.'⁷

A BMJ systematic 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.'⁸

The proposed legislation will cost millions.

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 ongoing communication), and healthcare training would be 'several millions'.⁹ All this would be at the expense of other more effective measures.

The proposed legislation is ethically problematic and highly controversial

⁶ How to Increase Organ Donation: Does Opting Out Have a Role? 2012, *Transplantation*, 93:2
http://journals.lww.com/transplantjournal/Abstract/2012/01270/How_to_Increase_Organ_Donation___Does_Opting_Out.3.aspx

⁷ How to Increase Organ Donation: Does Opting Out Have a Role? 2012, *Transplantation*, 93:2
http://journals.lww.com/transplantjournal/Abstract/2012/01270/How_to_Increase_Organ_Donation___Does_Opting_Out.3.aspx

⁸ 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>

⁹ 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>

As stated above, organ donation should involve the consent of the person whose body it was. 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. 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'.¹⁰

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. It can be seen in the Human Tissue (Scotland) Act 2006. The Human Tissue Authority, in its guidance in relation to the act, state:

'The 2006 Act is based on the principle of 'authorisation', an expression which is intended to convey that people have the right to express, during their lifetime, their wishes about what should happen to their bodies after death, in the expectation that those wishes will be respected. **It is a positive concept, representing a positive attitude to the issue, and replaces the 'lack of objection' approach embodied in the Human Tissue Act 1961, which the 2006 Act repeals for Scotland.**'¹¹

Donation for transplantation is one of the scheduled purposes where consent is required. It is crucial that this positive idea of authorisation is maintained.

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 culture, suffering from mental illness, dependent, those who have less ready access to information and those who change their minds?

¹⁰ 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).

¹¹ Human Tissue (Scotland) Act 2006: A Guide to its implications for NHSScotland, 2006, Human Tissue Authority, <https://www.hta.gov.uk/policies/human-tissue-act-2004>

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. It cannot be ensured, in practice, that every removal of human organs is appropriately authorised, even by the family.

When organ donation becomes 'presumed', it is no longer a voluntary gift, nor '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 the state. This may be a major issue, particularly among cultures whose respect for dead bodies preclude post death organ removal, such as followers of Shintoism.¹²

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.

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

Finally, 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.¹³ 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. To boost organ transplants there need to be more transplant co-ordinators, intensive care beds, organ retrieval teams and improved public awareness.

Question 2 - are there any changes you would make to the current 'opt in' authorisation system, other than moving to opt out?

We would propose for a return to a pure opt-in system, due to the ethical concerns surrounding opt-out systems, and would recommend the changes highlighted below.

Dr Rafael Matesanz, founder of the world's most successful transplantation service in Spain, 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.

'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

¹² <http://www.bbc.co.uk/religion/religions/shinto/shintoethics/organs.shtml>

¹³ 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/z4Q8FO>

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'.¹⁴

Also, we would agree with the recommendations of the report to improve public awareness of organ donations.¹⁵ In England, only 54% of people are aware of the Organ Donation Register and have a correct understanding of it, and 16% not even aware of the Register¹⁶ and the statistics are likely to be similar for Scotland. Therefore, there is a significant way to go before publicity as a way of encouraging more organ donations would be exhausted. There is an urgent to target Black and Minority Ethnic (BAME) groups, who are up to three times more likely to need a transplant than the wider population.¹⁷ While it is difficult to lump all of these minority ethnicities into one group, it represents a distinctive trend, with Pakistani, Bangladeshi, Black Caribbean, Chinese and African ethnicities being the most poorly represented on the Register, relative to the current UK population.¹⁸

Question 3 - where someone has joined the Organ Donor Register (ODR) or indicated in another way that they wish to donate, what do you think should happen if the potential donor's family opposes the donation?

CMF believes that, though family participation is crucial, they should not have a right to veto an organ donation if the deceased person has expressed an informed decision.

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)¹⁹. This principle implies that when the deceased's wishes are clear, the nearest relatives should not have a right of veto.

Question 4 - if there was a soft opt out system, what do you think of the proposed checks?

¹⁴ 'Increasing the supply of donor organs within the European Union', 2008, House of Lords Report, paragraph 192, <https://www.publications.parliament.uk/pa/ld200708/ldselect/lddeucom/123/123i.pdf>

¹⁵ 'A Donation and Transplantation Plan for Scotland 2013-2020' The Scottish Government, 2013, pp.22-23
<http://www.gov.scot/Resource/0042/00427357.pdf>

¹⁶ 'Understanding current attitudes and behaviours towards organ donation within England' NHSBT, 2013, p.42
<http://www.nhsbt.nhs.uk/to2020/the-strategy/supporting-documents/nhsbt-organ-donor-report-140813.pdf>

¹⁷ 'Taking Organ Transplantation to 2020: A UK strategy', NHSBT, 2013, p.10

http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_summary.pdf

¹⁸ Organ Donation and Transplantation data for Black, Asian and Minority Ethnic (BAME) communities: Report for 2015/2016, NHSBT, 2016, p.3

¹⁹ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10

[http://www.parliament.scot/S2_Bills/Human%20Tissue%20\(Scotland\)%20Bill/b42s2-introd-pm.pdf](http://www.parliament.scot/S2_Bills/Human%20Tissue%20(Scotland)%20Bill/b42s2-introd-pm.pdf)

We believe that these checks would not be sufficient.

A communication strategy necessary for an opt-out system would have to hit the entire population, and we do not believe that will possible to sustain long-term. Even at present, those living in Scotland may be unaware that their organs can be used for transplantation, even though they have not expressed any wish about the matter, if their nearest relatives give authorisation, under the terms of Section 7 (1) of the 2006 Human Tissue (Scotland) Act. The present consultation may be a side effect of this lack of knowledge. The 2008 Organ Donation Taskforce presents the issues behind the communication strategy of an opt-out organ donation system:

‘Such a campaign would require considerable resource (at least £45 million initially, with further reminder campaigns every few years and as new transplants become possible)... a lack of information would disadvantage those who wished to opt out but did not know how to do so. This might conceivably lead to legal challenge in the future.’²⁰

Question 4(a) - if you think these are not sufficient, what other checks would be needed (apart from those set out under step 3 below)?

We believe that the opt-out system, as a whole, is unethical, so cannot be seen as acceptable, no matter what checks are in place.

Question 5 - in any opt out system, what do you think should happen if a deemed authorisation donation was likely to distress the potential donor's family?

The donation should not go ahead. The Bristol²¹ and Alder Hey²² 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.

While we believe that a family does not have veto power if the deceased's wishes are clear (see Question 2), the family should be permitted to give consent, or withhold it, when there is any uncertainty about the deceased's wishes. Consent and trust underlies the relationship between a doctor and patients and their families.

Here are 5 reasons why CMF believes the donation should not go ahead:

²⁰ UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 31.

²¹ Keighley, M., The Spectre of Bristol, 2001, CMF Triple Helix
<https://www.cmf.org.uk/resources/publications/content/?context=article&id=1035>

²² Lucas, S. & Cook, R., Alder Hay, 2001, CMF Triple Helix,
<https://www.cmf.org.uk/resources/publications/content/?context=article&id=996>

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. The body is not simply raw material.

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 the family's. 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 fetal or embryonic tissue, for example²³) and so will look to their families to ensure that their specific wishes are carried out.

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. As mentioned already, 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 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.

²³ On the Ethics of Organ Transplantation: A Catholic Perspective, Anscombe Centre, 2014, pp.32-33
<http://bioethics.org.uk/Ontheethicsoforgantransplantationfinal.pdf>

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.

Question 6 - if there was a soft opt out system, what do you think about the categories of people set out for whom explicit authorisation would still be needed from the person themselves or family members

See Q14a for when we find it acceptable to provide consent within the opt-out system.

Question 6(a) - if these are not sufficient, why do you think this?

N/A

Question 7 - in what circumstances do you think an adult should be viewed as not having the capacity to make their own decisions about donation and therefore should not be subject to any deemed authorisation provisions?

We believe that if it cannot be assumed that an adult has full knowledge and understanding of the scheme, and its implications, then consent cannot be deemed to have been given. For specific guidance, please refer to Q1 and Q14a.

Question 8 - under what age do you think children should only be donors with explicit authorisation?

We think that anyone at any age should have explicit authorisation before donation, either from the donor themselves, or from family members who were absolutely certain that they were expressing the wish of the donor.

We also agree with the opinion of the Anscombe Centre (see more in our response to Q14):

'The consent of a parent or guardian, because of their interest in the represented person and their presumed love for them, preserves the notion of respect for the person who has died. Consent from a parent or carer is quite different from sequestration of bodies by the State without express consent of the deceased or of those who knew them best, in such a way that the bodies are seen as just a resource to be exploited by the State' (On the Ethics of Organ Transplantation: A Catholic Perspective, Anscombe Centre, 2014, pp.30-31
<http://bioethics.org.uk/Ontheethicsoforgantransplantationfinal.pdf>)

Question 9 - for children who are in care, what are your views on allowing a local authority which has parental responsibilities and rights for the child to authorise donation for the child if no parent is available?

N/A

Question 10 - in any opt out system, what provisions do you think should apply to the less common types of organs and tissue?

Though we oppose the opt-out system, we think there should be a differentiated system treating organs and their uses, as the use of different organs and tissues can carry with it different ethical considerations.

One of our particular concerns rests with fetal tissue, due to complicity with the practice of abortion (which opens up a whole additional section of ethical considerations) and embryonic tissue and stem cell lines,²⁴ due to our contention that adult stem cells are more promising and less ethically problematic than utilising embryonic stem cells for research.

We would also be concerned with the use of brain tissue as we agree with the Anscombe Centre's contention that:

'It would confuse individual identity either in relation to parenthood and procreation, or in relation to personal (psychological) identity'²⁵

And the distinction that arises between ordinary tissue and generative tissue (e.g. ovaries, testes, gametes), due to its containing the biological identity of the deceased person.²⁶

²⁴ On the Ethics of Organ Transplantation: A Catholic Perspective, Anscombe Centre, 2014, pp.32-33
<http://bioethics.org.uk/Ontheethicsoforgantransplantationfinal.pdf>

²⁵ Ibid., p.35

²⁶ Ibid., p.36

Question 11 - which tests do you think medical staff should be able to carry out on a donor before they withdraw life-sustaining treatment to check if their organs or tissue are safe to transplant, both where a patient's authorisation for donation is 'deemed', as well as where the donation is explicitly authorised:

N/A

Question 12 - if you answered no to some or all options in question 11, are there any circumstances when particular tests could be permitted?

N/A

Question 13 - where it is agreed a patient's condition is unsurvivable and it will not cause any discomfort to them, what do you think about medical staff being allowed to provide any forms of medication to a donor before their death in order to improve the chances of their organs being successfully transplanted, such as providing antibiotics to treat an infection or increasing the dose of a drug the patient has already been given [15]?

N/A

Question 14 - what do you think about allowing people to appoint one or more authorised representatives to make decisions for them?

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.²⁷ 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.²⁸

²⁷ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 12

<http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

²⁸ *ibid.*

Question 14(a) - if you think this should be allowed, in what circumstances do you think an authorised representative would be useful?

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

In terms of children, we agree with the opinion of the Anscombe Centre:

'The consent of a parent or guardian, because of their interest in the represented person and their presumed love for them, preserves the notion of respect for the person who has died. Consent from a parent or carer is quite different from sequestration of bodies by the State without express consent of the deceased or of those who knew them best, in such a way that the bodies are seen as just a resource to be exploited by the State.'²⁹

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.

Question 15 - do you have any other comments which you think should be taken into account in relation to any Scottish opt out system?

N/A

Question 16 - what do you think about providing CMO guidance to encourage clinicians to refer almost all dying or recently deceased patients - particularly those who are under 85 years old - for consideration as a potential organ or tissue donor?

N/A

Question 17 - what do you think about making it a procedural requirement for clinicians to involve a specialist nurse for organ donation, tissue donor coordinator or another individual with appropriate training in approaches to families about donation, wherever that is feasible?

²⁹ On the Ethics of Organ Transplantation: A Catholic Perspective, Anscombe Centre, 2014, pp.30-31
<http://bioethics.org.uk/Ontheethicsoforgantransplantationfinal.pdf>

We would agree there is a need for a specialist nurse to facilitate conversations on the topic of organ donations. In Spain, an important factor in increasing the number of donations in the country has been ensuring that the relatives of potential organ donors are always approached by someone specifically trained for the purpose, such as trained co-ordinators.³⁰

Question 18 - do you think there are particular impacts or implications for any equalities groups from any of the proposals in this consultation, either positive or negative? If yes, please provide details.

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 culture, 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. In terms of informing equality groups, the 2008 Organ Donation Taskforce suggested 'consideration would need to be given to the information needs of ethnic minorities, those with English as a second language, and hard-to-reach groups, such as the homeless,³¹ without which, consent cannot be appropriately claimed to have been given. 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. Further information can be found in our response to Q1.

³⁰ <http://www.publications.parliament.uk/pa/ld200708/ldselect/ldcom/123/123i.pdf>

³¹ UK Organ Donation Taskforce, The Potential Impact of an Opt Out System for Organ Donation in the UK, 2008, UK Department of Health Publications, p. 31.