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Date: 25 September 2014 – Ms. Anne McTaggart MSP

Consultation: ‘Organ and Tissue Donation (Scotland) Bill’

Consultation response on behalf of the Scottish Council on Human Bioethics:

The **Scottish Council on Human Bioethics** (SCHB) is an independent, non-partisan registered Scottish charity composed of doctors, lawyers, biomedical scientists, ethicists and other professionals from disciplines associated with medical ethics.

The principles to which the Scottish Council on Human Bioethics subscribe are set out in the **United Nations Universal Declaration of Human Rights** which was adopted and proclaimed by the UN General Assembly resolution 217A (III) on the 10th of December 1948.

The SCHB’s response can be shared internally with other Scottish Parliament policy teams who may be addressing the issues discussed. They may contact the SCHB again in the future and the SCHB gives permission to do so.

The SCHB is very grateful to Ms. McTaggart MSP for this opportunity to respond to the consultation on the **Organ and Tissue Donation (Scotland) Bill**. It welcomes her intention to promote public consultation, understanding and discussion on this topic.

Scottish Council on Human Bioethics Response

In the following response, the terms being used will be defined as:

Opt out systems: Systems which enable health care professionals to remove organs from every adult who dies – unless a person has registered to opt out. These may include:

- **Hard opt-out system** whereby organs can be removed even if relatives oppose the donation for a number of reasons. Example: Austria.
- **Soft opt-out systems** whereby organs are only removed when the closest relatives give their agreement at the time of death. This may happen even when closest relatives have no actual knowledge of the wishes of the deceased. Example: Spain.

Opt in systems: Systems which enables health care professionals to remove organs from persons who have opted into a register thereby making an explicit decision on the matter. These may include:

- **Soft opt-in systems** whereby organs can be removed though health care professionals may decide not to proceed if faced with opposition from relatives.
- **Hard opt-in systems** whereby organs may be removed even though closest relatives are opposed to organs being used for transplantation.

Opt-out systems whereby persons have to register their opposition to donation are often characterised as ‘presumed consent’ systems. However, the independent UK **Organ Donation Taskforce**, which was established by the UK Department of Health, indicated in its 2008 report entitled “**The Potential**

Impact of an Opt Out System for Organ Donation in the UK that “‘presumed consent’ is something of a misnomer in medical care because consent is in fact an active process in which permission is given by a patient for a procedure to be carried out on their body, thereby avoiding any possibility of clinical staff being guilty of an assault on the patient. Should a patient lack capacity and be unable to give consent for vital invasive procedures, doctors act on their judgement of the patient’s ‘best interests’, not on ‘a presumption’ of consent.”¹

The SCHB notes that what is characterised as a ‘presumed consent’ system cannot generally be defined as appropriate consent for all those from whom organs may be removed for transplantation. Because of this the SCHB cannot consider any opt-out system as ethically acceptable.

Question 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.

Scottish Council on Human Bioethics Response

The Scottish Council on Human Bioethics (SCHB) very much supports the consideration of new ways to increase the number of organs available for transplantation in Scotland and recognises the compassionate aims of Ms. McTaggart MSP in seeking to do this. However, it believes that the legislation being proposed is ethically inappropriate.

In the following sections the SCHB will examine the problems which presently exist with the legislative situation in Scotland. But the Council believes that only an opt-in instead of an opt-out system is an ethically appropriate solution for Scotland.

Problems with the Present Scottish Legislative Position

Contrary to the information presented in the consultation put forward by Ms. McTaggart MSP, Scotland arguably already has a *de facto* opt-out system.

Indeed, the ***Human Tissue (Scotland) Act 2006*** has created a hybrid system between the opt-in (explicit consent) and opt-out (often presented as presumed consent) systems for the removal of organs from a deceased person for transplantation. In other words, the proposed system in Scotland is of:

- (1) Informed consent (opt-in) for those who register their wish to donate a number of organs before death on the Organ Donor Registry or by carrying an organ donor card (though their nearest relatives may greatly add to this number of body parts being donated after death, without the informed consent of the deceased person, in conformity with Section 7 of the Act), and
- (2) A *de facto* soft opt-out (often presented as a presumed consent) system, similar to the Spanish system, when no prior wishes of the deceased person are known. Indeed, the general thrust of the soft opt-out system in Scotland enables nearest relatives to agree to the removal of organs from a deceased person when they have no “*actual knowledge that the adult was unwilling for any part of the adult’s body ... to be used for transplantation*” (using the words of the Scottish Act in Section 7).

This is confirmed in the Scottish Executive Press Release of the 30th of November 2005 leading up to the present legislation which indicated that a Consultant Surgeon at Edinburgh Royal Infirmary Transplant Unit, John Forsyth, said: “*These changes will make the legislation similar to the way in which Spanish law is put into effect.*”²

Basically, the Scottish system of obtaining organs is the one that would provide the greatest number of organs without having to go down the road of a hard opt-out system (with closest relatives having no say if a patient has not registered their opposition to donating organs) which most opt-out countries do

¹ 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. 11.

² 20 November 2005, <http://www.scotland.gov.uk/News/Releases/2005/11/30110629>

not accept since it is considered to be too traumatic for relatives. An example of the anguish caused by going down the route of hard opt-out system was experienced in Singapore in 2007.³

However, in contrast to all other systems of soft opt-out systems in Europe in which nearest relatives usually tend to give the final authorisation, the present Scottish Act does not enable persons, who wish to do so, to register their opposition to the removal of all or certain specific body parts after death. Indeed, the UK does not have a national register opposing general or specific organ donation.

In other words, a problem may arise if a person does not know or trust, his or her closest relatives, characterised in Section 50 of the **Human Tissue (Scotland) Act 2006** (and who may be just friends), concerning the decision to use his or her body parts after death. This person cannot stop his or her potentially unknown or unreliable relatives indicating that they have no “*actual knowledge that the adult was unwilling for any part of the adult’s body ... to be used for transplantation*” after death in the present Scottish context (using the words of the Scottish Act in Section 7).

Indeed, even in Ms. McTaggart MSP’s 2014 consultation document it is conceded that “*There is a risk the family may make a false statement about their knowledge of the deceased person’s wishes in order to give expression to their own view.*”⁴

The absence of fail-safe mechanisms to allow people to record their wishes, be they positive or negative, in the present Scottish Act is a cause of serious concern for the SCHB.⁵ The Council is even aware of a case where just a landlord of a deceased person in Scotland was asked to authorise the removal of organs for transplantation.

Moreover, in the context of what is believed, by many, to be a gradual disintegration of family and social structures in Scotland it is very questionable whether the nearest relatives mentioned in Section 50 of the **Human Tissue (Scotland) Act 2006** are aware of the wishes of the deceased person or even knew him or her when he or she was still alive.

Unfortunately, the present situation in Scotland has very serious ethical consequences and could lead to the undermining of the principle of informed consent in transplantation. As a result, it may undermine public confidence in the transplantation system and thereby reduce the number of available organs.

The SCHB is already aware of a number of single persons who have taken their names off the Organ Donor Register because they do not have any appropriate close relatives, as characterised in Section 50 of the Scottish Act, in which they can have confidence to implement their wishes after death.

Accordingly, it is the opinion of the SCHB that the present **Human Tissue (Scotland) Act 2006** may enable the same unacceptable mistakes to be made as in Alder Hey Children’s Hospital which would undermine public confidence in the organ transplantation system.

The SCHB also believes that Section 7 of this Act relating to the power of relatives to authorise the use of body parts of a deceased person who has not left any wishes may be open to a legal challenge at the European Court of Human Rights under the **European Convention of Human Rights** and specifically under:

- Article 8 (Right to respect for private and family life)
- Article 9 (Freedom of thought, conscience and religion)
- Article 10 (Freedom of expression)

Finally, in paragraph 102 of the Explanatory Report of the **Additional Protocol to the European Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin**⁶ it is indicated (under Organ and Tissue Removal from Deceased Persons) that:

³ Scuffle for organs sparks donor debate in Singapore – Reuters – 28.2.07 - <http://www.reuters.com/article/latestCrisis/idUSSIN173241>

⁴ Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p. 19.

⁵ *Organ Donation and Transplantation – SPICe Briefing – 1 June 2000* : http://www.scottish.parliament.uk/business/research/pdf_res_notes/rn00-40.pdf
Organ Donation – Experiences Internationally – SPICe Briefing – 16 June 2005 : <http://www.scottish.parliament.uk/business/research/briefings-05/SB05-82.pdf>

⁶ Explanatory Report: Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin paragraph 102. <http://conventions.coe.int/Treaty/en/Reports/Html/186.htm>

“It is the expressed views of the potential donor which are paramount in deciding whether organs or tissue may be retrieved.”

Thus, if a deceased person was not aware of (1) the system of consent/authorisation in place and (2) the possible destiny of his or her body or its parts (transplantation, research, etc.), and the use of the body or its parts did go ahead without the individual having given his informed consent, there may be grounds for taking the case to the European Court of Human Rights. This is because the **European Convention on Human Rights and Biomedicine** requires informed consent to take place before any intervention is envisaged. And, in this case, an intervention would also include a procedure after death under the spirit of the law.

Organ donor and transplant system

The SCHB considers it crucial that organs or tissue should only be removed from a deceased person if this person has given his or her prior informed consent to the procedure. In other words, if a system is 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 can only be considered as ethically unacceptable.

The SCHB believes that an opt-out system cannot make sure, from a practical perspective, that the very important informed explicit consent principle is always respected. In other words, it does not believe that what is called ‘presumed consent’ in the opt-out system can actually be defined as appropriate consent for all persons from whom organs may be removed when they die.

In the case of an opt-out system, the closest relatives could be able to authorise the removal of body parts. But this would only be ethical if the closest relative was absolutely certain that the deceased person was aware of the opt-out system and had not objected to the procedure. The possibility for the closest relatives to authorise the retrieval of organs when an individual has left no wishes should not be possible.

The SCHB is extremely concerned about the potential for serious mistakes resulting from the possibility of a closest relative authorising the removal of body parts from a deceased person who has not left any specific expression of wishes.⁷ This is because there is no certainty that the decisions of a closest relative are a true reflection of the wishes of the person at the time of his or her death.

To go beyond the express and specific wishes of a person by letting others make important decisions on what they ‘assume’ or ‘presume’ are the wishes of this person is what specifically led to the scandal at Alder Hey Children’s Hospital in Liverpool. 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 opt-in, informed consent, system should be implemented in Scotland - Not the opt-out system

The SCHB notes that, in Scotland, over the five year period 2008-2013, 62% of donations have come from donors who were not on the register at the time of their death.⁸ In these cases, it was the nearest relatives who gave the authorisation to donate organs. Many of these would have had no actual knowledge that the deceased was willing or unwilling to donate body parts after his or her death.

Because of this situation, the SCHB would like to see the present legislation in Scotland reformed so as to only enable the opt-in, explicit consent, system to be implemented. In this it agrees with the 2008 Independent Report from the UK **Organ Donation Taskforce** which indicates that:

⁷ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 12., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

⁸ A Donation and Transplantation Plan For Scotland 2013-2020, <http://www.scotland.gov.uk/Publications/2013/07/7461/4>

“[A]fter examining the evidence, the Taskforce reached a clear consensus in recommending that an opt out system should not be introduced in the UK at the present time. The Taskforce concluded that such a system has the potential to undermine the concept of donation as a gift, to erode trust in NHS professionals and the government, and negatively impact on organ donation numbers. It would distract attention away from essential improvements to systems and infrastructure and from the urgent need to improve public awareness and understanding of organ donation. Furthermore, it would be challenging and costly to implement successfully. Most compelling of all, we found no convincing evidence that it would deliver significant increases in the number of donated organs.”⁹

This would also confirm the conclusion from the 2008 **House of Lords** report on the matter which indicated that *“[O]n the basis of the evidence we have heard during our inquiry, we do not believe that a convincing case has yet been made for an immediate move to a presumed consent system in the UK.”¹⁰*

Ethical Perspective

It was noted by some commentators, in the 2008 **House of Lords** report that even explicit consent could only be effective if the wishes of the deceased person had been reliably and directly expressed near the time of death and these adequately reflected the wishes of the person. Where this was not the case, the closest relatives would usually have to rely on guesswork about the deceased’s wishes, which would weaken the system.¹¹

The 2008 UK **Organ Donation Taskforce** noted that:

“The Human Tissue Authority’s guidance is clear that consent is a positive rather than a passive process, which equips the prospective donor with the information needed to make a decision. Therefore, the change from opt in to opt out for transplant purposes could risk undermining the ... consent provisions, which safeguard the rights of individuals or their families to be asked if tissue can be used for a variety of other purposes. The Human Tissue Authority was very concerned that a change to the consent requirements for one activity could result in the destabilisation of the consent provisions for other activities.”¹²

It then noted that:

“The [Ethics Working Group of the Organ Donation Taskforce] recognised that there were problems with the current system. It is hard to argue that signing the Organ Donor Register is an act of ‘informed consent’, as the term is more broadly understood, but it is clearly intended as an act of authorisation. If a person has not registered their wishes formally, in the absence of a clear conversation taking place, a family can only do their best to establish what someone would have wanted. If there is uncertainty, the family carry the responsibility for deciding what to do on an uninformed basis, which is unsatisfactory regardless of the choice they make.

Uncertainty about a potential donor’s wishes is at the heart of difficulties with the current system, yet uncertainty could remain an issue with an opt out system. It may not be appropriate to assume that all those who have failed to opt out have no objection to becoming donors, given the real possibility of apathy and/or disorganisation preventing them signing the opt out register. The group was not convinced that evidence of widespread support, as expressed in opinion surveys, could necessarily support a claim that all those who fail to opt out actively intend to donate.

⁹ 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. 34.

¹⁰ House of Lords, European Committee, *Increasing the supply of donor organs within the European Union*, Vol. 1: Report, 2008, The Stationery Office, p. 78.

¹¹ House of Lords, European Committee, *Increasing the supply of donor organs within the European Union*, Vol. 1: Report, 2008, The Stationery Office, p. 54.

¹² 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. 18.

To sum up, the group did not have any fundamental moral objections to a system of authorisation based on checking an opt out register. However, they felt that an improved opt in system, or possibly even a system where people were required to make the choice to opt in or opt out, would provide a basis on which to proceed with a greater degree of certainty about an individual's wishes and would therefore be more acceptable."¹³

It also indicated that:

*"There is no fundamental moral objection to opting out as a means of recording individual wishes regarding donation, but there are reasons to prefer an improved opt in system as a means of removing uncertainty and thereby facilitating donation."*¹⁴

As the Taskforce report indicated, this is because:

*"With an opt out system, not registering may mean that someone's organs are taken when they had serious objections to this happening."*¹⁵ Adding: *"There are issues about recording the wishes of those who do not engage with the UK's institutions and systems, including those with limited capacity and hard-to-reach groups."*¹⁶

The SCHB is, therefore, of the opinion that any opt-out organ procurement system which allows the removal of organs from deceased persons who have not previously made known their refusal could give rise to unethical practices. For the notion of consent to be meaningful, the public must have been duly informed as soon as persons reach the age of decision making! However, 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'.¹⁷ It is therefore fundamentally deceitful to rely solely on alleged 'presumed consent'.

The SCHB also agrees that it would be extremely difficult for absolutely everyone in Scotland to be aware of the system in place. Promises that advertising and publicity campaigns will be undertaken to promote the message that people should not simply carry a donor card or put their name on the Organ Donor Register, but also let their nearest relatives know of their wishes¹⁸, will never be sufficient. Talking about death can still be considered taboo in many sections of Scottish society and members of the general public are entitled to not have to address this topic.

In this regard, it was noted that UK subjects are encouraged to make choices but they are also allowed the right not to make choices.¹⁹ For example, as with the present voting system at elections, people are entitled and have the right, in Scotland, not to make a specific decision. Thus, it would be unacceptable for electoral officers, after an election, to ask the nearest relatives of those who did not vote (either directly or using a proxy) to 'presume' the wishes of those who did not vote and thereby cast a vote for them. It would be even more dangerous for a political party in government to pass legislation in parliament indicating that any person who had not cast a vote in an election can be 'presumed' to have voted for this party. Again it should be emphasised that a 'presumed consent' system cannot be considered as appropriate consent.

¹³ 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. 15.

¹⁴ 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. 16.

¹⁵ 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. 19.

¹⁶ 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. 20.

¹⁷ 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 (article written in Hungarian), cited by Aniko Smudla MD, Katalin Hegedus Ph.D., Semmelweis University, Institute of Behavioural Studies, Budapest).

¹⁸ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 13., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

¹⁹ 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. 13.

This was acknowledged in the Policy Memorandum of the **Human Tissue (Scotland) Bill** in 2005, where, in paragraph 22, it was indicated that:

*“the public’s reaction to the revelations about organ retention at post-mortem examination shows that, for many people, presumed consent does not represent a valid form of consent. They feel it deprives them of a sense of control over what happens to their bodies, or the bodies of their loved ones, after death.”*²⁰

Indeed, many witnesses who gave evidence to the 2008 **House of Lords** Report on the matter were clear that consent should be explicit. For example, the organisation **Patient Concern** rejected the suggestion of presumed consent system since it considered such a system as “no consent at all”.²¹ In this regard, Ms Joyce Robins, writing on behalf of **Patient Concern**, stated that “Presumed consent would turn us from volunteers into conscripts—unless we register as conscientious objectors ... Such a system would make the term ‘donation’ redundant. A donation is something freely gifted, not taken by default”.²²

The SCHB is, therefore, extremely alarmed about the new opt-out legislation being proposed for Scotland. This is because “the presumption will be that the deceased had no objection to donation – since, if they had, they would have registered that objection during their lifetime, and this would have been a straightforward thing for them to do.”²³ However, as Ms McTaggart’s consultation document acknowledges “There will remain a degree of uncertainty when there is no entry in the opt-out register but those who strongly opposed transplantation are likely to have registered an objection, so the family may feel more confident in not objecting and may have less uncertainty to deal with.”²⁴ But the SCHB is concerned that such a statement is not supported by any research or published evidence and could lead to unethical organ removal procedures taking place.

Deceased Person’s wishes should be respected

The SCHB 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).²⁵ This principle implies that when the deceased’s wishes are clear and valid, the nearest relatives should not have a right of veto.

Any decision that may go against the real wishes of the deceased person would enable a very unethical situation to exist.²⁶ Authorisation from the nearest relative to remove organs from a deceased person would only be acceptable if the relative was absolutely certain that the deceased person was 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. Any legislation which resulted in only one decision being made by a nearest relative which did not reflect the real wishes of a deceased person could be considered as enabling unethical practices to exist.

Legal Perspective

²⁰ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 22., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

²¹ House of Lords, European Committee, Increasing the supply of donor organs within the European Union, Vol. 1: Report, 2008, The Stationery Office, p. 54.

²² House of Lords, European Committee, Increasing the supply of donor organs within the European Union, Vol. 1: Report, 2008, The Stationery Office, p. 59.

²³ Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p. 19.

²⁴ Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p. 19.

²⁵ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

²⁶ In the Additional Protocol to the European Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin²⁶ it is indicated that: “It is the expressed views of the potential donor which are paramount in deciding whether organs or tissue may be retrieved.”

The 2008 **Organ Donation Taskforce**, which was established by the UK Government, indicated that:

“Were an opt out system to be introduced, a communications strategy would need to be devised to ensure that all those people who wished to opt out entirely, or to opt out of the donation of particular organs or tissues, knew how to do so. In addition, communications would be needed to outline arrangements for special groups such as children, those lacking capacity and visitors to the UK. 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. The media campaign would need to be extensive both in its use of different forms of media and in its duration (over at least two years, prior to and after enactment of legislation). Such a campaign would require considerable resource (... with further reminder campaigns every few years and as new transplants become possible). The effectiveness of this campaign would need to be evaluated on a regular basis to identify any deficiencies. 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.”²⁷

The 2008 Taskforce noted that *“some people are concerned that a proportion of the 10% to 35% of the population who would not have wished to donate their organs, but never got round to registering an objection, could mistakenly be considered as willing donors under an opt out system.”²⁸*

The Taskforce also indicated that simply having a register where people could record their decision (opting either in or out) during their lifetime would probably be insufficient to ensure compliance with the **European Convention on Human Rights** because:²⁹

- In an opt-out system, it could result in organs being taken from those who had not yet managed to register an objection, perhaps because they were simply busy or disorganised. They might also have learning difficulties or other problems with communication, such as English as a second language; and
- In an opt-in system, the deceased may have registered a wish to donate a long time ago and since changed their mind, but had not got round to taking their name off the register.

Any system must allow for taking evidence from family members about the deceased’s latest wishes and beliefs if these are known. If the law were to be changed to an opt out system, this would be necessary to enable the presumption of consent to be rejected if there was evidence that the deceased did not wish to be a donor, even though he or she had not recorded this decision on a register. If this were not provided for, the Taskforce believes that there would be a significant risk of successful legal challenge.³⁰

The SCHB is of the view that the Scottish government should ensure that it respects the following international legislation.

Council of Europe

(1) Convention on Human Rights and Biomedicine CETS No.: 164.³¹

Entered into force on 1 December 1999

²⁷ 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.

²⁸ 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. 8.

²⁹ 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. 12.

³⁰ 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. 12.

³¹ Convention on Human Rights and Biomedicine, <http://conventions.coe.int/Treaty/en/Treaties/Word/164.doc> - Legally binding if ratified by a country - The United Kingdom has not signed nor ratified this Convention

(2) Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin CETS No.: 186

Entered into force on the 1st of May 2006.

(3) Convention on Action against Trafficking in Human Beings CETS No.: 197

Entered into force on the 1st of February 2008.

As with the **Hague Convention on the International Protection of Adults (with Incapacity)**³², the SCHB would like to see the United Kingdom ratify, as soon as possible, the above Council of Europe legal instruments on behalf of Scotland.

European Union

(4) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells

(5) Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

Clinical Perspective

Over the last five years the number and proportion of people in Scotland on the NHS Organ Donor Register has increased markedly - from 29% in 2007/08 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.³³

The 2008 UK **Organ Donation Taskforce** noted that:

“A system of decision making which is based on respecting the known wishes of the patient is the one that is most likely to maintain the integrity of the relationship between doctors and patients and between doctors and the wider public, and maintain trust and confidence in the donation system.

According to the intensive care society’s survey, intensivists are evenly split as to whether an opt out system should be introduced, but the strength of feeling among those who are opposed is considerable.”³⁴

The Taskforce also noted that:

“The Clinical Working Group of the Organ Donation Taskforce heard from a number of clinicians from intensive care (where the majority of deaths leading to donation occur) who were persuasive in articulating the view that a presumption of consent might make families feel that they were being pressured and erode the relationship of trust between clinician and family.”³⁵

Adding that:

“An opt out system has the potential to erode the trust between clinicians and families at a distressing time. The concept of a gift freely given is an important one to both donor families and transplant recipients. The Taskforce feels that an opt out system of consent has the potential to undermine this concept.”³⁶

³² Legally binding if ratified by a country - Adopted on 13 January 2000 but has not yet entered into force. The United Kingdom has ratified the Convention on 5 November 2003 (but for Scotland only).

³³ A Donation and Transplantation Plan For Scotland 2013-2020, <http://www.scotland.gov.uk/Publications/2013/07/7461/4>

³⁴ 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. 17.

³⁵ 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. 17.

³⁶ 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. 17.

Communication Perspective

The SCHB is concerned that persons are sometimes not adequately informed of what is involved when they consider donating their bodies or their parts after death for purposes such as transplantation. For example, the SCHB is aware that many individuals do not realise that this may include a face or reproductive cells as well as tissue. Thus the Council would like to see better information being available to the Scottish general public in order to enable the important principle of 'informed consent' to exist.

The SCHB notes that Ms. McTaggart MSP's 2014 consultation document indicates that in Scotland:

"[I]n up to 15% of cases, the opportunity to remove organs or tissues from people who were on the organ donor register is lost because their families refuse consent.³⁷ In fact families refuse consent in around 43% of cases where donation would be possible.³⁸ This refusal rate has not changed since 2008 and the UK has one of the highest refusal rates in the Western world. Spain in contrast has a refusal rate of less than 20%.³⁹" The document adds that in the UK: *"Where the deceased's wishes are unknown the family refusal rate rises further to 57%.⁴⁰"*

Even the Policy Memorandum of the draft **Human Tissue (Scotland) Bill** - when it was being discussed in 2005 - accepted that nearest relatives were 'changing their mind' with respect to what they believed were the wishes of the deceased person when these have not been communicated.⁴¹

In addition, the SCHB noted that proxies were very bad at substituting judgement for others and that often only a random chance existed of making the same decision. Indeed, studies showed that spouses who had not discussed organ donation between them, mis-assumed the real wishes of their partner with respect to organ donation at a level of nearly 50%.

More research is also required to examine whether the real donation wishes of persons in countries where an opt-out system is already in place are, in fact, appropriately represented in that country.

As already noted, in Scotland, about 40% of the population is on the organ donor register though over 90% of Scottish people support organ donation.⁴²

In this regard, questions can be asked relating to the reasons for this discrepancy. Moreover, should this discrepancy be respected as reflecting a difference between good intentions and actual decision making? This is a difficult question since the principle of informed consent does not relate to intentions but decisions.

Question 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?

Scottish Council on Human Bioethics Response

The SCHB believes that there is still a lot to be done to increase the opt-in organ donation rate. It would also like to examine whether the change in the Welsh legislation has been effective in increasing the donation rate. It would be inappropriate to change to a system that may not provide real advantages.

³⁷ http://www.nhsggc.org.uk/content/default.asp?page=s1240_38

³⁸ http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_long.pdf

³⁹ <http://www.parliament.uk/business/publications/research/briefing-papers/POST-PN-441/organ-donationand-transplants>

⁴⁰ <http://www.parliament.uk/business/publications/research/briefing-papers/POST-PN-441/organ-donationand-transplants>

⁴¹ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

⁴² Ms. A. McTaggart MSP, Proposed Organ and Tissue Donation (Scotland) Bill Consultation Document, 2014, p.11.

The 2008 UK **Organ Donation Taskforce** identified a number of barriers to donation – for example, lack of awareness, laziness, unwillingness to think about death, a lack of trust in medical professionals and concerns about how donors are treated.⁴³ However, the SCHB believes that these are surmountable within the current legal system.

The Taskforce also indicated that “*The public engagement work undertaken suggests that numbers on the Organ Donor Register could be increased at a relatively modest cost through a more extensive publicity and engagement programme, perhaps akin to that for blood donation.*”⁴⁴

Question 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.

Scottish Council on Human Bioethics Response

In an informed consent (opt-in) system, which is the only system which can be considered ethical, from a practical perspective, the family should always be consulted if they are the ones who know the last wishes of the deceased. In the case where the deceased was a person lacking capacity to make a decision to donate organs, the nearest relative should be able to authorise or forbid the removal of organs.

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

Scottish Council on Human Bioethics Response

The SCHB believes that an individual should be able to appoint a proxy to make the final decision regarding transplantation on their behalf.

The SCHB agrees that if there is no closest relative and no expression of wishes by the deceased, there should be no role for the ‘person lawfully in possession of the body’ to make a decision on organ retrieval since he or she cannot reflect the wishes of the deceased person. Therefore, in these circumstances no organ retrieval should take place.

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

Scottish Council on Human Bioethics Response

The SCHB disagrees that the opt-out system is ethically appropriate since it cannot ensure that every procedure of organ retrieval respects the principle of informed consent for persons from whom organs would be removed.

The SCHB agrees that in relation to adults and children aged 16 or older, the carrying of an organ donor card, or the registering of their names on the Organ Donor Register should be sufficient indication of the individuals’ wishes. Verbally expressed wishes should be witnessed by two persons who are assured that the person has the capacity to make such a decision.

⁴³ 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. 20-21.

⁴⁴ 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. 32.

Question 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?

Scottish Council on Human Bioethics Response

As already indicated, the SCHB agrees that in relation to adults and children aged 16 or over, the carrying of an organ donor card, or the registering of their names on the Organ Donor Register should be sufficient indication of the individuals' wishes. Verbally expressed wishes should be witnessed by two persons who are assured that the person has the capacity to make such a decision.

The only instances where authorisation from a closest relative may be considered when the wishes of a deceased person are not known are when the person is a child or a person who did not have the capacity to consent to such a procedure while still alive. This would then reflect the provisions in the ***European Convention on Human Rights and Biomedicine*** whereby Article 6 (Protection of persons not able to consent) states that:

“2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The individual concerned shall as far as possible take part in the authorisation procedure.”

Question 7: Do you agree the soft opt-out system should apply to people who have been resident in Scotland for a minimum period of 1 year prior to their death? Please indicate “yes/no/undecided” and explain the reasons for your response.

Scottish Council on Human Bioethics Response

The SCHB disagrees that the opt-out system is ethically appropriate since it cannot ensure that every procedure of organ retrieval respects the principle of informed consent.

In an opt-in system persons could donate an organ after death even if they were resident for less than a period of one year prior to their death.

Question 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?

Scottish Council on Human Bioethics Response

See above.

Question 9: Do you think 6 months is a long enough period to run a campaign prior to change over?

Scottish Council on Human Bioethics Response

See above

Question 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?

As noted in Ms. McTaggart MSP's consultation document, the average annual cost of dialysis for a patient with kidney failure is £30,800 but a successful kidney transplant operation costs £17,000 and £5,000 thereafter.⁴⁵ The **NHS Blood and Transplant** predicts that for every year a kidney transplant remains functional, the NHS saves £24,100 per patient.⁴⁶ However, the SCHB is of the opinion that it is not because a procedure can save lives or a lot of money that it automatically become ethical. Other principles may have priority such as the concept of the inherent human dignity of a person and the system of informed consent.

Question 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?

Scottish Council on Human Bioethics Response

With an opt-out system it is very likely that only persons who are appropriately informed of such issues will be aware of the actual system in place. This may represent only a certain category of person resulting in inequality relating to the manner in which the real wishes of a person are expressed, recognised and respected.

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

Scottish Council on Human Bioethics Response

Presumed consent alone will not solve the organ shortage.

The 2008 **House of Lords** report noted that: "*Dr Rafael Matesanz, Director of the Spanish Organ Donation Office, argued strongly that organisational changes were much more important for increasing donation rates than presumed consent. "Opting in, opting out in my opinion means nothing". He explained that, although the presumed consent system had been in place since 1979, organ donation rates in Spain had remained low until changes to the organisational structure had started to be made in 1989.*"⁴⁷

The SCHB would like to see a follow up of all the recommendations presented by the 2008 **Organ Donation Taskforce** report entitled ***Organs for Transplants*** which indicated that these recommendations "*taken together, would create a structured and systematic approach to organ donation in the UK. The Taskforce believes their implementation would save the lives of at least 1,000 people each year and dramatically improve the quality of life for hundreds more, and for their families.*"⁴⁸

Before any changes in the law are considered, the SCHB would also like to see a follow up report of the implementation of the recommendations from the **Scottish Government's** document ***Transplantation Plan For Scotland 2013-2020.***⁴⁹

The SCHB is of the opinion that organ donation must always be a donation made free of charge in a spirit of solidarity; that organ procurement must never be decided on financial grounds and that a human organ must never be considered or treated as a commodity.

The SCHB also agrees that it would be preferable to invest in raising the profile of the Organ Donor Register and improving transplantation infrastructure instead of considering an opt-out system.

⁴⁵ http://www.organdonation.nhs.uk/newsroom/fact_sheets/cost_effectiveness_of_transplantation.asp

⁴⁶ http://www.organdonation.nhs.uk/newsroom/fact_sheets/cost_effectiveness_of_transplantation.asp

⁴⁷ House of Lords, European Committee, Increasing the supply of donor organs within the European Union, Vol. 1: Report, 2008, The Stationery Office, p. 59.

⁴⁸ Organ Donation Taskforce, Organs for Transplants, 2008, UK Department of Health, p. 52.

⁴⁹ Scottish Government, Transplantation Plan For Scotland 2013-2020, <http://www.scotland.gov.uk/Publications/2013/07/7461/0>

Scope of the proposed Bill

The scope of the proposed Bill is unclear but the transplantation of (1) reproductive organs, tissue and cells and (2) embryonic or foetal organs, tissue and cells from the deceased should be prohibited.

Required Request

The possibility of enabling 'required requests', in which staff in intensive care environments must *always* approach the family about organ donation when medical treatment has stopped and death has been confirmed by brain stem tests, should be supported.

It may then encourage more positive attitudes within the NHS by taking away the feeling that complying with a request for organ donation should be done as a favour to the transplant unit.

Other comments

The SCHB agrees that future Scottish legislation should include a 'friend of long-standing' in the hierarchy of 'relatives' but it should also make sure that the relevant person is an extremely close friend with a friendship lasting over several years.

The SCHB supports the proposal that the new legislation should include a provision to put beyond doubt the legality of taking the minimum action necessary to preserve a human body so that consultation on transplantation can take place.

It would be useful to have up-to-date data relating to transplantation statistics. The SCHB notes, for example, that the graph in the consultation document relating to organ donations around the world dates from 2002.