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Inquiry for the Organ Donation Taskforce

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

The SCHB subscribes to the principles set out in the United Nations Universal Declaration of Human Rights which was adopted and proclaimed by the UN General Assembly by resolution 217A (III) on 10 December 1948. The SCHB is grateful to the West Midlands NHS for this opportunity to respond to the consultation on organ donation and transplantation. It welcomes the Committee's intent to promote public consultation, understanding and discussion on transplantation.

In addressing the consultation, the SCHB has formulated the following responses, which can be made publicly available by the Committee:

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

Scottish Legislative Perspective

1. In Scotland, the ***Human Tissue (Scotland) Act 2006*** has created a hybrid system between the explicit consent (opt-in) and presumed consent (opt-out) 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 NHS 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) 'soft' presumed consent (opt-out), similar to the Spanish system, when no prior wishes of the deceased person are known. Indeed, the general thrust of the 'soft' presumed consent 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).
2. Basically, the Scottish system of consent is the one that would provide the greatest number of organs without having to go down the road of 'hard' informed consent (relatives having no say if patient has not said anything) which most 'presumed consent' countries do 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' presumed consent was recently experienced in Singapore¹.
3. However, in contrast to all other systems of 'soft' presumed consent in Europe in which nearest relatives usually tend to make the final decision, the 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 relatives, characterised in Section 50 of the ***Human Tissue (Scotland) Act 2006*** (and who may be just friends), concerning the decision

¹ Scuffle for organs sparks donor debate in Singapore – Reuters – 28.2.07 - <http://www.reuters.com/article/latestCrisis/idUSSIN173241>

to use his or her body parts after death. Indeed 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 UK context (using the words of the Scottish Act in Section 7).

The absence of fail-safe mechanisms to allow people to record their wishes, be they positive or negative, in the Act is a cause of serious concern for the SCHB².

4. The SCHB is even aware of a case where just a landlord of a deceased person was asked to authorise the removal of organs for transplantation in Scotland.
5. 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 even aware of the wishes of the deceased person.
6. 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.
7. The SCHB is already aware of a number of single persons who are considering taking their names off the NHS Organ Donor Register. This is 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.

Organ donor and transplant system

8. The SCHB has not taken a position concerning whether or not an ‘opting in’ or ‘opting out’ scheme would be preferable in possible future Scottish legislation. However, 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 unethical.
9. The possibility for the next of kin to authorise the retrieval of organs when an individual has left no wishes should not be possible in an ‘opting in’ i.e. informed consent system. If body parts are removed without any explicit prior informed consent of the deceased person, then the procedure would be unethical. In the case of an ‘opting out’ system, the next-of-kin could be able to authorise the removal of body parts. But this would only be ethical if the next-of-kin was absolutely certain that the deceased person was aware of the ‘opting out’ system and had not objected to the procedure.
10. The SCHB agrees that in relation to adults and mature children, the carrying of an organ donor card, or the registering of their names on the NHS 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.

Defining Death

11. The SCHB is of the view that specific provisions should exist which enable the physician removing the organs for transplantation to be satisfied that brain stem death tests have been performed adequately and duly recorded in an appropriate manner.
12. The SCHB also agrees that physicians should never be under pressure of hastening the death of a person in order to remove organs for transplantation as has recently been the case in the USA³. Care for the dying patient should never be undermined or dictated by the potential for organ donation.

² 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>

13. There are also serious concerns in defining non-heart-beating death following a case in France in 2008 whereby a 45 year old man recovered after having been defined as dead under this criteria. Indeed, it was only because surgeons authorised to remove organs for transplant operations were not immediately available that the man was able to be saved⁴.

Required Request

14. 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.

Paired Donation

15. Since live kidney donation could be increased by paired donation, the SCHB notes that this procedure should be considered for any new legislation. Two potential pairs, hampered by blood group incompatibility, would then be able to exchange kidneys between pairs (for example, donor A, who is incompatible with recipient A, gives to recipient B, and donor B gives to recipient A).

Altruistic Donation

16. The possibility of 'altruistic' donation, whereby a member of the public expresses a wish to donate a body part, such as a kidney, to the national pool of potential recipients should also be taken into account, provided the donor is not subjected to any serious harm to himself or herself and after (1) providing extensive counselling to the potential donor and (2) obtaining informed consent.

Deceased Person's wishes should be respected

17. 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 NHS Organ Donor Register)⁵. This principle implies that when the deceased's wishes are clear, the nearest relatives should not have a right of veto.
18. However, 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, medical research and education or training. For example, the SCHB is aware that many individuals do not realise that this may include the dissection of a naked body in front of large number of undergraduate medical students. 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.
19. Studies show that around 90% of the UK population would be willing to donate organs after their death, yet only 11.3 million out of a UK population of 59.2 million are registered on the NHS Organ Donor Register (as at May 2004)⁶. 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.
20. Even the Policy Memorandum of the draft **Human Tissue (Scotland) Bill** - when it was being discussed - 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. Indeed, in paragraph 10 it stated that:

³ New Zeal in Organ Procurement Raises Fears, Washington Post, September 2007: <http://www.washingtonpost.com/wp-dyn/content/article/2007/09/12/AR2007091202681.html?hpid=topnews>

⁴ John Lichfield, 'Dead' patient comes around as organs are about to be removed, The Independent, 12 June 2008, www.independent.co.uk/.../dead-patient-comes-around-as--organs-are-about-to-be-removed-845140.html

⁵ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-introd-pm.pdf>

⁶ Human tissue and organs – shortages, <http://www.bma.org.uk/ap.nsf/Content/Humantissueorgansshortages>

“For reasons which are not entirely clear, but which may be related to the effect of issues surrounding retention of organs at post-mortem examination, in ... Scotland, the relatives’ refusal rate where the deceased’s wishes are not known has risen from just over 30% in the early 1990s to around 49% now⁷.”

21. The SCHB agrees that if there are no next-of-kin, organ and tissue retrieval should only take place on the basis that the deceased person carried a donor card or had registered his or her decision on the NHS Organ Donor Register.

No removal of body parts should take place when the wishes of the deceased person are unknown

22. Any decision that may go against the real wishes of the deceased person would enable a very unethical situation to exist⁸. The removal of organs from a deceased person would only be acceptable if the nearest 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 even 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.
23. The SCHB is extremely concerned about the potential for serious mistakes resulting from the possibility of a ‘nearest relative’ authorising the removal of body parts from a deceased person who has not left any specific expression of wishes⁹. This is because there is no certainty that the decisions of a ‘nearest relative’ is a true reflection of the wishes of the person at the time of his or her death.
24. 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 lead 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.
25. 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 Register, but also let their nearest relatives know of their wishes¹⁰, 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.
26. As with the present voting procedure 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.
27. The only instances where authorisation from a nearest 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:

⁷ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 10., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-intro-dpm.pdf>

⁸ In the Additional Protocol to the European Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin⁸ 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.”*

⁹ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 12., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-intro-dpm.pdf>

¹⁰ Policy Memorandum, Human Tissue (Scotland) Bill, paragraph 13., <http://www.scottish.parliament.uk/business/bills/pdfs/b42s2-intro-dpm.pdf>

“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.”

28. If there are no nearest relatives 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 wished of the deceased person. Therefore, in these circumstances, no organ retrieval should take place.

Organ Trafficking

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

United Nations

(1) Protocol to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children, supplementing the United Nations Convention against Transnational Organized Crime

This Protocol entered into force on the 25th of December 2003.

(2) Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography

This Protocol entered into force on the 18th of January 2002.

In order to combat organ trafficking the SCHB supports **extra-territorial provisions** making it an offence for habitual residents in Scotland going abroad to undertake transplantation procedures which are prohibited in Scotland. Precedent has already been established in this regard with Article 4 of the UN **Optional Protocol to the Convention on the Rights of the Child on the sale of children, child prostitution and child pornography**.

Council of Europe

(3) Convention on Human Rights and Biomedicine CETS No.: 164

Entered into force on the 1st of December 1999¹¹.

(4) 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.

(5) 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)**¹², 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.

¹¹ Legally binding if ratified by a country - The United Kingdom has not signed and not ratified this Convention

¹² 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).

European Union

(5) 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

(6) Draft European Parliament Legislative Resolution on the Initiative of the Hellenic Republic with a view to adopting a Council Framework Decision concerning the prevention and control of trafficking in human organs and tissues (7247/2003 – C5-0166/2003 – 2003/0812(CNS))