



SCOTTISH EXECUTIVE

Health Department
Directorate of Service Policy and Planning

Health Planning and Quality Division
St Andrew's House
Regent Road
Edinburgh EH1 3DG

Contact List: see attached

Telephone: 0131 244 2420

18 March 2004

Dear Sir/Madam

CONSULTATION PAPER ON THE LEGISLATION RELATING TO ORGAN AND TISSUE DONATION AND TRANSPLANTATION

I am writing to invite comments on proposals for new legislation in Scotland relating to organ and tissue donation and transplantation. The existing legislation is contained in the Human Tissue Act 1961 and the Human Organ Transplants Act 1989. The subject matter of these Acts is not reserved to the Westminster Parliament. This consultation parallels those dealing with legislation on hospital post-mortem examinations (published on 24 November 2003) and the Anatomy Act 1984 (published on 28 January 2004). The outcome of all of these consultations will inform the development of legislation to be introduced in the Scottish Parliament when a suitable opportunity occurs.

The proposals take account of parallel consideration in the rest of the UK of the law relating to organ and tissue donation and transplantation, in order to ensure broad consistency of approach. The Human Tissue Bill, which contains details of the legislation proposed for the rest of the UK, can be found on the website of the Department of Health in London, at www.doh.gov.uk/tissue. This follows the consultation on the Department of Health/Welsh Assembly Government report *Human Bodies, Human Choices* (July 2002). A more detailed description of the relevant provisions of the Bill is given in paragraphs 31 and 32. The Bill would repeal for England, Wales and Northern Ireland the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989.

Transplantation of organs and tissue involves their retrieval from people who are still alive as well as from people who have died. Each category is governed by different legislation, and raises different considerations. This consultation paper is therefore in 2 main parts. The first part deals with transplantation from people who have died. The second part deals with transplantation of organs from those who are still alive. The third part concerns tissue banking.

For the purposes of this consultation, it should be noted that blood, and any products derived from blood, are excluded from its scope. This is consistent with the Human Tissue Bill, which excludes blood and blood products from the regulatory scope of the Human Tissue Authority.

Consultation process

We would be grateful if you would structure your comments according to the layout of the consultation document, as this will allow us to consider and analyse all responses in a comprehensive and prompt manner. Please also feel free to give us your views on any other aspects of the proposed legislation.

A web version of the Consultation Paper can also be accessed at www.scotland.gov.uk/views/views.asp. You can telephone Freephone 0800 77 1234 to find out where your nearest public internet access point is, if you prefer to submit your response by email. This should be sent to: transplantationconsultation@scotland.gsi.gov.uk

Submission of Responses

Responses to this consultation should be submitted by **Friday 11 June 2004** to:

Ms Cheryl Paris
Health Planning and Quality Division Branch 4
Scottish Executive Health Department
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If you have any queries, contact Cheryl Paris at 0131-244 2946.

To help inform debate on the points covered by this consultation paper, the Scottish Executive intends to follow its normal practice of making copies of responses received available to the public in the Scottish Executive library at Saughton House, Broomhouse Drive, Edinburgh (tel 0131 244 4552) by 23 July 2004. If respondents indicate that they wish all, or part, of their reply excluded from this arrangement, confidentiality will be strictly respected. All responses not marked confidential will be checked for any potentially defamatory material before being placed in the Scottish Executive library. To assist us in handling your response appropriately, it is important that you complete the attached 'Respondee Information Form' at Annex A.

An outline list of consultees is attached at Annex B. If there are other individuals or bodies who should be included, please either copy the Paper directly to them, or ask the Departmental contact (as indicated above) to send them a copy.

I look forward to receiving your views on this consultation.

Yours faithfully



W S SCOTT

RESPONDEE INFORMATION FORM

Please complete the details below and attach it with your response. This will help ensure we handle your response appropriately:

Name:

Address:

Title of consultation:

1. Are you responding as:

- an individual
on behalf of a group or organisation

2. Do you agree to your response being made public (in SE library and/or on SE website)?

- Yes
No

Where confidentiality is not requested, we will publish your full response including your name (and address, where provided).

If you do not wish these personal details to be published, please tick this box:

Are you content for the Scottish Executive Health Department to contact you again in the future for consultation purposes?

- Yes
No

The Scottish Executive Consultation Process

Consultation is an essential and important aspect of Scottish Executive working methods. Given the wide-ranging areas of work of the Scottish Executive, there are many varied types of consultation. However, in general, Scottish Executive consultation exercises aim to provide opportunities for all those who wish to express their opinions on a proposed area of work to do so in ways which will inform and enhance that work.

While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body. Consultation exercises may involve seeking views in a number of different ways, such as public meetings, focus groups or questionnaire exercises.

Typically, Scottish Executive consultations involve a written paper inviting answers to specific questions or more general views about the material presented. Written papers are distributed to organisations and individuals with an interest in the area of consultation, and they are also placed on the Scottish Executive web site enabling a wider audience to access the paper and submit their responses¹. Copies of all the responses received to consultation exercises (except those where the individual or organisation requested confidentiality) are placed in the Scottish Executive library at Saughton House, Edinburgh (K Spur, Saughton House, Broomhouse Drive, Edinburgh, EH11 3XD, telephone 0131 244 4552).

The views and suggestions detailed in consultation responses are analysed and used as part of the decision making process. Depending on the nature of the consultation exercise the responses received may:

- indicate the need for policy development or review
- inform the development of a particular policy
- help decisions to be made between alternative policy proposals
- be used to finalise legislation before it is implemented

If you have any comment about how this consultation exercise has been conducted, please send them to:

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¹ www.scotland.gov.uk

LIST OF CONSULTEES

Accident and Emergency Departments, Scotland
Action of Churches Together in Scotland
Africa Centre Scotland
Age Concern Scotland
Asian Concern
Asian Welfare Association
Associated Presbyterian Churches of Scotland
Association for Children with Heart Disorders
Association of Clinical Pathologists
Baptist Union of Scotland
Black & Minority Ethnic Elders Group
BMA Scottish Office
British Association of Tissue Banks
British Liver Foundation
British Lung Foundation
British Organ Donor Society (BODY)
British Paediatric Pathology, Scottish Branch
British Transplantation Society
Church of Scotland
Churches Agency for Inter-faith Relations in Scotland
Citizens Advice Scotland
Commission for Racial Equality
Confederation of Scotland Council of Christian & Jews
Confederation of Scotland's Elderly
COSLA
CRUSE Bereavement Care
Department of Biomedical Sciences, University of Aberdeen
Department of Forensic Medicine & Science, University of Glasgow
Department of General Practice, University of Edinburgh
Department of Health, London
Department of Pathology, Western Infirmary, Glasgow
Disability Rights Commission
Equal Opportunities Commission
Ethics & Advisory Committee, Royal College of Paediatrics and Child Health
European Members of the Parliament
Evangelical Alliance Scotland
Faculty of Advocates
Free Church of Scotland
Free Presbyterian Church of Scotland
General Medical Council
Head of Biological & Clinical Laboratory Sciences, University of Edinburgh
Head of Bute Medical School, University of St. Andrew's
Head of Life Sciences, University of Dundee
Health & Community Care Committee, Scottish Parliament
Help the Aged Scotland

Hospital Chaplains Association
Justice for the Innocents
Link Nurses
Local Authority Chief Executives
Local Health Councils
Local Research Ethics Committees
Medical & Dental Defence Union of Scotland
Medical Research Council
MRC Social & Public Sciences Unit, University of Glasgow
National Kidney Research Fund
National Services Division of Common Services Agency
Neuropathology Department, University of Edinburgh
NHS Board Chief Executives
NHS Board Medical Directors
NHS Health Scotland
NHS Trust Chief Executives
NHS Trust Medical Directors
Office of the Chief Rabbi
Participants of the Non-heartbeating Donation Conference
Participants of the Organ Donation Conference
Procurators Fiscal Society
Professor Sheila McLean, University of Glasgow
Reform of Synagogues of Great Britain
Reformed Presbyterian Church of Scotland
Religious Society of Friends (Quakers)
Retained Organ Commission
Roman Catholic Church
Royal College of Anaesthetists
Royal College of General Practitioners
Royal College of Nursing, Scottish Branch
Royal College of Paediatrics and Child Health
Royal College of Pathologists, London
Royal College of Physicians & Surgeons of Glasgow
Royal College of Physicians of Edinburgh
Royal College of Surgeons of Edinburgh
Royal Society of Edinburgh
Scottish Association of Chaplains in Healthcare
Scottish Churches Parliamentary Office
Scottish Civic Forum
Scottish Cot Death Trust
Scottish Council for Voluntary Organisations
Scottish Council, Royal College of Pathologists
Scottish Deans of Medical Schools
Scottish Episcopal Church
Scottish Executive Library
Scottish Federation of Kidney Patients Association
Scottish Intensive Care Society
Scottish Inter-faith Council
Scottish Law Commission
Scottish Medico-legal Society

Scottish National Blood Transfusion Service
Scottish Organisation Relating to the Retention of Organs (SORRO)
Scottish Partnership Forum
Scottish Pensioners Association
Scottish Pensioners Forum
Scottish Regional Council, Institute of Biomedical Sciences
Scottish Transplant Co-ordinators Network
Scottish Transplant Group
Scottish Transplant Support Network
SPICe
Stillbirth and Neonatal Death Society (SANDS)
The Institute of Biomedical & Life Sciences, University of Glasgow
The Law Society of Scotland
The Patients Council
Transplants in Mind (TIME)
UK Central Council for Nursing, Midwifery and Health Visiting
UK Transplant
United Free Church of Scotland
Voluntary Sector Health Network
Welsh Assembly Government
West of Scotland Seniors Forum

Individual members of the public who have written to the Minister on related matters and individual members of the public and health professionals who request a copy.

Legislation Relating to Organ and Tissue Donation and Transplantation

A CONSULTATION PAPER

Part 1: Transplantation of Organs and tissue from people who have died

Background

1. This review of the legislation takes place against a background of an acute shortage of donor organs for transplantation. At the end of 2003, there were 450 people in Scotland on the waiting list for an organ, 418 of whom were waiting for a new kidney, 20 for a new pancreas, and 20 for either a heart or a liver. (The numbers waiting for a heart or a liver reflect the fact that no alternative treatment exists, whereas those waiting for a kidney will be on dialysis.)
2. The position regarding tissue is similar. Tissue which can be donated includes bones, bone marrow and stem cells (including cord blood), tendons, heart valves, skin and corneas. There are intermittent shortages of most tissues.
3. Organs need to be retrieved and transplanted within a few hours of death. They cannot be stored. Tissue can be retrieved from people up to 24 hours after death, and can be stored in tissue banks for up to 10 years in some instances.
4. Organ and tissue retrieval for transplantation purposes usually takes place when the potential donor dies in hospital in circumstances in which he or she can be maintained on a ventilator, so that the circulation of the blood can be continued until such time as a team arrives to retrieve the organs and tissue. The process of retrieval cannot begin until death has been confirmed by brain stem tests carried out by 2 doctors independently of one another and of the transplant team. Once organs have been retrieved, they are allocated across the UK by UK Transplant. Tissues in Scotland are sent to the Scottish National Blood Transfusion Service's Tissue Bank for processing (where necessary), storage and release for therapeutic use.
5. Organs, mainly kidneys, but also liver and lung, can be retrieved from 'non-heartbeating donors'. The first situation which lends itself to this type of retrieval is where a patient is certified dead on arrival at hospital, or dies in the accident and emergency department. For donation of organs to take place, steps have to be taken to preserve the kidneys until the family can be contacted to establish whether the deceased had expressed any wishes on the subject. A small catheter is introduced into the main artery in the groin and this is used to 'perfuse' the kidneys. This is a special technique, which has to be started within minutes of death, in which the kidneys are flushed with a cold preservation fluid. This type of non-heartbeating donation is called 'uncontrolled' because of the limited time in which discussions about organ donation can take place.
6. Non-heartbeating donation can also take place as a 'controlled' procedure. This is where a patient is critically ill, often in an intensive care unit (ICU), and a decision is made jointly by the relatives and the medical team that aggressive therapy should be curtailed or withdrawn. There is time for discussion with the relatives at this point about whether organ donation should proceed. Following death, which is confirmed by conventional means, organ perfusion can be carried out with cold preservation solution, and the organs removed in the

usual manner for the purposes of transplantation. Tissue from such donors can be obtained up to 24 hours after death without any need for perfusion.

7. The law governing the retrieval of organs and tissue from those who have died (referred to in this Consultation Paper as ‘cadaveric donors’) is the Human Tissue Act 1961, which also makes provision for hospital post-mortem examinations. For transplantation, it ‘makes provision with respect to the use of parts of bodies of deceased persons for therapeutic purposes’. Section 1(1) of the 1961 Act provides that if the deceased expressed a request in recognised form that his body, or any specified part of it, should be used after death for therapeutic purposes, the person lawfully in possession of the body (this is not defined in the Act, but is generally understood as being the hospital administrator if the person died in hospital) can authorise the removal from the body of any part, or such part as was specified by the deceased. In practice, the hospital needs to have evidence of the deceased’s wishes, and these have to be either in writing, which can be done at any time, or orally in the presence of at least 2 witnesses during the deceased’s last illness. The power given to the person lawfully in possession of the body is discretionary, and the decision whether to exercise the power, and the factors to be taken into account in reaching that decision, rest with the person lawfully in possession of the body.

8. Section 1(2) of the 1961 Act provides that the person lawfully in possession of the body may authorise the removal of any part of the body for therapeutic purposes if, having made such reasonable enquiry as may be practicable, he has no reason to believe that the deceased had expressed an objection to his body being so dealt with, and had not withdrawn the objection, or that the surviving spouse or any surviving relative of the deceased objects to the body being so dealt with.

9. This is different from the regime governed by the Anatomy Act 1984, under which an adult can request that his or her body should be used after death for anatomical examination. As noted in the covering letter, there is a separate consultation on the provisions of the 1984 Act.

10. The present system of organ donation across the UK is referred to as one of ‘opting in’, which means that the individual has taken a positive decision in favour of donating organs and tissue after death for purposes of transplantation. The alternative system, known as ‘opting out’ or ‘presumed consent’, is based on the supposition that organs and tissue can be retrieved after death for transplantation provided the dead person had not registered an objection to that happening.

11. The law relating to cadaveric organ donation and transplantation in Scotland has already been the subject of consultation. The Scottish Transplant Group’s *Organ Donation Strategy for Scotland* was published in July 2002 on a consultative basis. It contained a discussion of the Human Tissue Act 1961 and made a number of recommendations:

- that the system of opting-in should be strengthened by placing the emphasis, in discussions with relatives, on determining what wishes, if any, the deceased might have expressed;
- that, in anticipation of a change in the law, ‘relatives’ should be understood as meaning those closest to the potential donor in life;
- that the carrying of an organ donor card and/or registering on the NHS Organ Donor Register should be regarded as an advance directive (i.e. the wishes of the deceased should be fulfilled wherever possible); and

- the Human Tissue Act 1961 should be replaced by separate legislation governing organ retention and organ donation/transplantation. This echoed a recommendation of the Review Group on Retention of Organs at Post-Mortem.

12. As the report of the Scottish Transplant Group pointed out, there are a number of reasons for wanting to look at the provisions of the 1961 Act in the context of cadaveric organ donation:

- both the Scottish Transplant Group and the Review Group on Retention of Organs at Post-Mortem drew attention to the fact that having a single piece of legislation governing organ donation *and* hospital post-mortem examinations has been a source of confusion in the public mind. Families affected by past hospital post-mortem examination organ retention have indicated strong support for organ donation, and concern at the confusion of the 2 issues;
- the role of the ‘person lawfully in possession of the body’ is unclear;
- because of difficulties in interpreting the 1961 Act in the transplantation context, hospitals have had problems with the role of the surviving spouse and relatives. It is good practice to approach the surviving spouse and/or relatives to establish an absence of objection on the part of the deceased, and that there are no medical reasons why donation would be inadvisable. This applies with even greater force to tissues. Because they are not necessarily used in a life-saving situation, there is more time to make sure they are safe to use. In practice, the way in which the transplant community approaches the issue of organ donation tends to suggest that the decision whether to proceed with retrieval rests with the relatives. In strict legal terms, this goes beyond the provisions of section 1 of the Act. It also opens up the possibility of the deceased’s wishes, as expressed by carrying a donor card, being vetoed by the relatives;
- as noted in the Consultation Paper on hospital post-mortem examinations, the 1961 Act fails to acknowledge the reality of many contemporary relationships which may, for example, not involve marriage or may be of the same sex.

13. In theory, the provisions of the 1961 Act could be retained for Scotland so far as they relate to organ donation and transplantation. This has the virtue of simplicity, and would also allow a longer look to be taken at future legislation in this area. It is doubtful, however, how tenable such an option would be, given the drawbacks of the 1961 Act. There would be a strong danger that public confidence would be undermined simply because this important area of activity had been left to operate under legislation which is otherwise seen as inadequate and out-of-date. The Executive therefore proposes to proceed on the basis that the 1961 Act should be repealed in its entirety and new legislation developed in its place for cadaveric organ and tissue retrieval.

Question 1:

In the light of the legislation being proposed for the rest of the UK, and in Scotland in respect of hospital post-mortem examinations, do you agree there should be new legislation in Scotland in respect of organ and tissue transplantation?

14. Although some respondents, particularly the British Medical Association, argued for a move towards a system of ‘opting out’ (see paragraph 10), responses to the consultation showed general support for the basic approach of strengthening the system of opting in by giving greater emphasis to fulfilling the wishes the individual had expressed in life. The Scottish Transplant Group argued that there is little evidence to suggest that a system of

opting out necessarily increases the supply of organs, except in countries such as Austria where there is a strong tradition of the state taking responsibility for disposal of the body. It is important that any changes to the legislation should help to maintain positive attitudes towards organ and tissue donation and transplantation, and such a change would need to command the support of a strong majority of the public and healthcare professionals. Evidence of such support is currently lacking.

15. The Executive believes that the new legislation for Scotland should be firmly based on respecting the autonomy of deceased individuals, provided they had the capacity to make their wishes known. This is in line with the Scottish Transplant Group's recommendations aimed at strengthening the current system of opting in, which is also the basis of the legislation proposed for the rest of the UK.

16. The considerations here are the same as those relating to hospital post-mortem examinations. The Executive therefore believes that the concept of 'authorisation' is as valid in the organ donation context as it is in the context of the hospital post-mortem examination. The process of 'authorisation' suggests an active decision by someone in a recognised position of power. For a fuller discussion of the concept, see paragraphs 10-12 of the Consultation Paper on Hospital Post-Mortem Examinations. The introduction of the concept is in keeping with the general move towards making patients and carers equal partners in health care decisions. The use of this term can also be seen as a continuation of a concept inherent in the 1961 Act, which refers to the person lawfully in possession of the body being able to 'authorise' a hospital post-mortem examination.

17. Extending the concept of authorisation to cadaveric organ and tissue donation would have the following advantages:

- It would fulfil the recommendation of the Scottish Transplant Group that the carrying of an organ donor card and/or registering on the NHS Organ Donor Register should be regarded as a form of advance directive carrying with it the implication that the wishes of the deceased should be fulfilled. Whereas very few people think to express a wish for a post-mortem examination, millions of people have taken the decision to carry an organ donor card or put their name on the NHS Organ Donor Register maintained by UK Transplant. Recent research indicates that many of those who carry cards or have registered believe that organ and tissue donation will follow automatically, should the circumstances arise, and are dismayed when told that their relatives might be able to veto their intentions. The principle of autonomy would mean that the deceased's wishes should indeed be paramount. This is consistent with the fundamental principle which will apply in the rest of the UK. The Review Group advised in the post-mortem examination context that this approach should be coupled with a campaign aimed at getting people to talk to those closest to them about their intentions. The Executive launched on 16 February 2004 just such a major advertising campaign in respect of organ donation. The same principle also underpins the Organ Donation Teaching Resource Pack which we published on 3 November 2003. The arrangements would be broadly as proposed for hospital post-mortem examinations: checking if the deceased had left any wishes, and, if not, asking the person closest to the deceased in life what his/her wishes would have been. Details of this are set out in the next paragraph;
- the Scottish Transplant Group was also keen that 'relatives' should be understood as meaning those closest in life to the potential donor, and that aim would be achieved by adopting the hierarchy proposed in the next paragraph. This would be much clearer than the arrangements under the 1961 Act;

- there is already considerable consistency about the forms transplant and tissue co-ordinators use when seeking consent to organ donation. These could be adapted quite readily to the language of ‘authorisation’ and would thereby be strengthened;
- The carrying of donor cards and registering on the NHS Organ Donor Register provides a clear and accessible mechanism for recording the individual’s wishes during his or her lifetime which does not exist in the post-mortem examination context. The public would need to be confident, however, that the Register was kept current and checked regularly, especially to remove names where someone had changed their mind about donation.

18. The effect of the application of the concept of authorisation to cadaveric organ donation can be summarised as follows:

Children:

- Organs and tissues would not be retrieved from deceased children unless this was authorised by a parent or the parents. Retrieval would not take place if the parents disagreed between themselves about whether to authorise it. These arrangements would also apply in the case of a mature child (see paragraph 20 of the Consultation Paper on Hospital Post-Mortem Examinations) who had expressed no views on the subject;
- authorisation would be recorded on a suitably adapted version of the forms which transplant and tissue co-ordinators have already devised and which are in general use across Scotland.

Adults and Mature Children:

- organs and tissues would be retrieved if that was the expressed wish of the individual adult, competently made before death, either in writing or verbally, at any stage in adult life;
- organs and tissues would not be retrieved where an adult with capacity expressed a wish that this should not happen, and had not changed his or her mind as far as the next-of-kin were aware;
- the hospital should still make reasonable enquiries as to whether or not those wishes had been withdrawn. ‘Reasonable enquiries’ would mean consulting whoever would have been approached to authorise the retrieval if the deceased had not left any wishes on the subject;
- where the individual left no wishes, the next-of-kin would be able to authorise the retrieval of organs. ‘Next-of-kin’ should be defined by means of a hierarchy consisting of:
 - spouse, including registered civil partner;
 - partner (including same-sex and unmarried couples);
 - child;
 - parent;
 - brother or sister;
 - grandparent;
 - grandchild;
 - uncle/aunt;
 - niece/nephew;
 - person who has been living with the adult for 5 years or more.

This hierarchy replicates that in recent Mental Health legislation. Authorisation should be obtained from the person whose relationship to the deceased comes highest in this hierarchy. Where 2 or more people are ranked equally, it would be sufficient to obtain authorisation from any one of them.

19. These proposals are broadly consistent with the ‘informed consent’ approach being developed for the rest of the UK. There would no longer be a role for the ‘person lawfully in possession of the body’ (except possibly in relation to preservation for transplantation: see paragraph 41).

20. One significant difference from the hospital post-mortem examination context is that it seems unnecessary to provide, in respect of organ donation and transplantation, that the individual could nominate one or more representatives who would have the power to authorise the organ retrieval, notwithstanding any subsequent loss of capacity on the part of the individual. It is difficult to imagine circumstances in which a person in favour of organ donation would choose the indirect approach of nominating someone to make that decision after the individual’s death, rather than simply carrying an organ donor card or adding their name to the Register. There is also potential for confusion, if not conflict, where there could be both an expression of wishes and a nominated person. It should be noted, though, that the Human Tissue Bill will allow the individual’s expression of wishes to take precedence over the views of a nominated representative.

Question 2:

Should the system of organ and tissue donation in Scotland rest on the concept of ‘authorisation’?

If someone has decided to carry an organ donor card or add their name to the NHS Organ Donation Register, is there any role for a nominated person?

21. The autonomy of the individual would not allow the family any right of veto, but it is recognised that the co-operation of the family is needed in order to obtain a social and medical history. Where organ retrieval went ahead in spite of objections by the family, relations between ICU staff and the transplantation team could be compromised, and there might be adverse media coverage which would have an adverse impact on the whole of transplantation. The legislation proposed for the rest of the UK is on the basis that consent gives authority to remove organs and tissues, but does not oblige that to happen.

22. The number of such cases of conflict between the wishes of the individual and the family is likely to be very small. Research shows that while in some parts of the country up to 78% of relatives can refuse to agree to organ donation where the views of the deceased are not known, most accept that organ donation should go ahead when provided with evidence that that was the deceased’s wish. It may also be re-assuring to point out that the proposed arrangements mean that where the deceased had left no clear wishes about organ donation but the relatives were vehemently opposed, organ retrieval would not go ahead because the next of kin who ranked first in the hierarchy would have the right to refuse to give the necessary authorisation.

23. In this context it is also worth pointing out that relatives who have lost a loved one often derive great benefit from the fact that a gift has been made and that some good has therefore come to others out of the tragedy that has befallen them. The arrangements proposed for the new legislation are intended to preserve this sense of altruism, especially in cases where the organ retrieval was authorised by a member of the next-of-kin hierarchy.

24. The hierarchy of relatives included in paragraph 18 is broadly similar to that in the legislation proposed for the rest of the UK, except that that legislation makes provision at the foot of the list for a ‘friend of longstanding’. No definition for this term is given in the Bill, but a Code of Practice would be published by the Human Tissue Authority.

25. The proposed approach outlined in the previous paragraphs raises a number of questions, which are set out below.

Question 3:

In respect of *children*, what provision should the new legislation make for situations where the parents take a different view on whether organ retrieval should go ahead, or where the hospital has been dealing with only one of the parents?

Question 4:

In relation to *adults* and *mature children*, should the carrying of an organ donor card, or registering his or her name on the NHS Organ Donor Register be sufficient indication of the individual’s wishes, or should some further proof be required? If so, what form should that further proof take? How should verbally expressed wishes be witnessed?

Question 5:

If there are no next-of-kin, should organ and tissue retrieval take place on the basis that the potential donor carried a donor card or had registered on the NHS Organ Donor Register? If there are no next-of-kin and no expression of wishes by the deceased, should there continue to be a role for the ‘person lawfully in possession of the body’, or in those circumstances should organ retrieval simply not proceed?

Question 6:

Should the legislation attempt to balance the wishes of the deceased against those of the surviving relatives, where these are in opposition?

Question 7:

Should there be a separate Register for those who wish to record their objection to organ donation?

Question 8:

Should the Scottish legislation include ‘friend of longstanding’ in the hierarchy of ‘relatives’? If so, for how long should the friendship have lasted for these purposes?

26. The question then arises what types of enforcement, if any, should apply to cadaveric organ and tissue retrieval. Enforcement could take the form of criminal sanctions, a system of licensing or a system of inspection.

27. Criminal sanctions. It has been one of the criticisms of the 1961 Act that it contains no penalties for breach of its terms. The Consultation Paper on Hospital Post-Mortem Examinations proposes criminal penalties for failing to obtain authorisation, or failing to abide by the terms of the authorisation given. In considering whether it would be appropriate to apply these penalties to cadaveric organ and tissue retrieval, a number of points should be borne in mind:

- in sharp contrast to organ retention at post-mortem examination, there has never been any scandal associated with the process of cadaveric organ and tissue retrieval. This procedure enjoys the support of the great majority (90%) of the public, and the imposition of penalties might raise unfounded concerns;
- the national transplantation services (heart, liver, combined kidney and pancreas) are monitored by the National Services Division of the Common Services Agency of NHSScotland, and in relation to kidney transplantation NHS Quality Improvement Scotland has developed clinical standards. All of organ and cornea donation and transplantation is overseen by UK Transplant. Tissue donation and use in Scotland are overseen by the Scottish National Blood Transfusion Service, which is fully accredited by the Medicines and Healthcare Products Regulatory Authority. Collectively, these arrangements provide effective protection against any abuse of the system;
- all of transplantation is subject to the general rules of clinical governance, as with any other hospital procedure.

28. In the light of these considerations, we do not propose to introduce a system of regulation or penalties in relation to the retrieval of organs and tissue from cadaveric donors for purposes of transplantation. In reaching this conclusion, we are aware that this embodies a difference of approach from the legislation proposed for the rest of the UK.

Question 9:

Are there reasons for wanting to apply the penalties proposed in the hospital post-mortem examination context to cadaveric organ and tissue retrieval?

29. One aspect of cadaveric organ retrieval which has attracted penalties, however, is trafficking in organs. The Human Organ Transplants Act 1989 in broad terms is designed to prevent the making or receiving of payment for organs for transplantation, or the placing of adverts inviting people to supply organs for transplantation in exchange for payment. The penalty provisions for breaching the provisions of the Act are imprisonment for up to 3 months and/or a fine. Under the Human Tissue Bill, the maximum penalty would be 3 years' imprisonment and a fine. We would propose to continue these penalties, but at the same level as in the Human Tissue Bill, in the new legislation for Scotland. This issue is discussed further in Part 2 of the Consultation Paper, which deals with living donation.

30. Other forms of supervision and enforcement include systems of inspection and regulation. In considering the relevance of these to Scotland, it is necessary to look at the proposals in the legislation for the rest of the UK.

31. That legislation proposes the establishment of a Human Tissue Authority, the functions of which would cover the full range of uses of human organs and tissues dealt with by the legislation. These would include post-mortem examinations as well as organ and

tissue retrieval, and from the living as well as the dead. The Authority would have broad functions of maintaining a statement of general principles, providing general oversight and guidance, superintending compliance with the requirements of the legislation and codes of practice made under it, providing information to the public, monitoring developments and advising Ministers in the other countries of the UK.

32. The Human Tissue Authority would have 2 subsidiary bodies, one an Inspectorate of Anatomy and Pathology, the other an Inspectorate of Organs and Tissue for Human Use. The Inspectorate of Organs and Tissue for Human Use would have within its remit activities relating to the removal from a human body of material for transplantation, the use, storage, import and export and disposal of that material. Our understanding is that in practice this Inspectorate's activities would relate in particular to live transplants and tissue banking, both of which subjects are discussed below.

33. Extension to Scotland of these arrangements in relation to cadaveric organ donation and transplantation would achieve consistency of approach. This is particularly important, given that organs for transplantation must continue to be shared across the whole of the UK in order to obtain the best match and therefore the best outcomes for recipients. The same consideration applies to tissues. Chronic shortages often mean that they have to be shared across the border.

34. On the other hand, the new legislation for the rest of the UK is not intended to affect the day-to-day operational activities of UK Transplant (UKT), as there is no intention of licensing the processes of retrieving organs for donation or the implantation of those organs in recipients. Nor would there be anything in the legislation which would affect UKT's status as a Special Health Authority, and therefore impact on its status as a cross-border public authority in terms of the Scotland Act 1998 (the Cross-Border Public Authorities (Specification) Order 1999). UKT and the Human Tissue Authority will need to discuss issues such as Codes of Practice governing specific aspects of transplantation. The consequence of these in respect of Scotland would need to be assessed.

35. As it seems unlikely that the Human Tissue Authority will have any day-to-day role in the business of cadaveric transplantation, it is not proposed to extend its functions to Scotland in the context of *cadaveric* organ and tissue transplantation.

Question 10

Should some or all of the functions of the Human Tissue Authority in respect of cadaveric transplantation be extended to Scotland? If so, which functions?

Other Issues Relating to Transplantation

36. Section 1(4) of the Human Tissue Act 1961 provides that a doctor undertaking the removal of organs for transplantation is required to satisfy himself 'by personal examination of the body that life is extinct'. It is not clear that this provision serves any useful purpose in cases where death is diagnosed by brain stem criteria. Doctors independent of the transplant team will perform the necessary tests; if the criteria are met, the patient is pronounced dead. There seems to be no reason for the transplant surgeon to replicate the tests, though he or she

should of course have to be satisfied that the brain stem death tests have been performed adequately. This provision of the 1961 Act has not been carried forward into the Human Tissue Bill. In relation to non-heartbeating donation, however, there are grounds for arguing that the provision of the 1961 Act should be continued. In these cases, death is confirmed by conventional means and by doctors independent of the transplant team who have been involved in caring for the patient during his or her life. As an additional safeguard, the retrieving transplant surgeon should be satisfied that death has been certified in the usual way.

Question 11:

Should the new legislation proposed for Scotland continue the provision of the 1961 Act requiring the doctor removing organs for transplantation to satisfy himself that life is extinct, or should there be specific provision that he should satisfy himself that the brain stem death tests have been performed adequately? Should the provision be retained if it is decided that organs and/or tissue could be retrieved by someone acting under the direction of a registered medical practitioner? (see paragraphs 37-40)

37. Section 1(4A) of the 1961 Act allows eyes, or parts of eyes, to be removed by a registered medical practitioner or a person in the employment of a Health Board or NHS Trust acting under the direction of a registered medical practitioner. The legislation proposed for the rest of the UK will not carry forward this restriction, on the grounds that there is no technical necessity for the removal of organs or tissue always to be carried out by a medical practitioner and that removal could be done by another suitably qualified person, such as a tissue bank technician.

38. In relation to the retrieval of *organs* for transplantation, such a change might appear sit oddly with the backing which the Scottish Transplant Group and NHS Quality Improvement Scotland have given to the development of a single national organ retrieval team. The *raison d'etre* for such a team is that the quality of retrieved organs requires specialised surgical skills, since the better the quality of the organs retrieved, the better the outcomes are likely to be for the recipients. These considerations might suggest that organ retrieval should continue to be done by a registered medical practitioner. It could also undermine confidence in the transplantation process if the new legislation allowed this procedure to be undertaken by someone other than a registered medical practitioner.

39. On the other hand, it is possible that a member of theatre staff, trained to a very high level, could, under supervision, remove organs. This would help to address the implications for retrieval teams of the EU Working Times Directive. The change in the legislation for the rest of the UK could also lead to circumstances in which, for example, a retrieval team from England, including non-doctors, might be sent to retrieve organs in Scotland because no-one in Scotland was available to do so. It would seem sensible that the Scottish legislation should allow for this eventuality, rather than run the risk of organs not being retrieved because the law in Scotland had not been changed to allow non-doctors to retrieve organs.

Question 12:

Should the new legislation in Scotland allow for the retrieval of organs under the supervision of a registered medical practitioner?

40. In relation to the retrieval of *tissue*, tendons and other tissues are currently retrieved by specialists such as orthopaedic surgeons, plastic surgeons and pathologists. As there are no technical factors equivalent to those in the organ retrieval context, such retrieval could be undertaken by non-medical teams, provided they were adequately trained and under the supervision of a registered medical practitioner. The new legislation should therefore not stand in the way of such a development.

Question 13:

Should the new legislation in Scotland allowing for retrieval of tissue under the supervision of a registered medical practitioner?

41. Preservation for transplantation. The new legislation for the rest of the UK will make clear that it is lawful for the person in charge of a hospital, nursing home or other institution to preserve a body or part of a body so that transplantation can take place. In doing so, the person concerned must take the minimum steps necessary and use the least invasive procedure. This provision is designed to deal with the need to consult those closest to the potential donor to make sure, as far as possible, that there is no reason why donation may be inadvisable. In some circumstances, such as after an accident, it may take some time to contact relatives. If steps are not taken to preserve the organ, the possibility of donation may be lost. The Scottish legislation should include a similar provision. It has the additional advantage of helping to raise public awareness about the possibility of such steps being taken after death, which means that relatives may be better prepared when they are approached.

Question 14:

Is there general support for 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 body so that consultation on transplantation can take place?

42. The situation envisaged when considering the making of such a provision has to be distinguished from the practice known as ‘elective ventilation’, which involves placing on life support a patient who is very likely to die, with the aim of preserving the organs for transplantation. Elective ventilation has been considered unlawful on the grounds that a patient’s right to give or withhold consent to treatment extends only to treatment intended to benefit the patient him- or herself. If the patient is unconscious, treatment can be given in the absence of consent, but only to the extent necessary to save the patient’s life, and provided it is not against the patient’s known wishes. The Executive does not plan to include any provision on this subject in the new legislation, since it does not directly involve the removal, retention or use of organs.

43. ‘Required request’. At present, it is at the discretion of the medical staff whether to approach the family to discuss organ and tissue donation. Families who are not approached may feel that they are denied the right to make a decision about organ donation. In the USA, it is the law that a request for organ donation must be made, in appropriate circumstances, after death. This is known as ‘required request’, and means that 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. It has been argued that such an approach encourages 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. It emphasises instead that it is the right of the individual that the possibility of organ donation should be considered, and is consistent with an approach based on authorisation.

Question 15:

Should new legislation in Scotland make provision for ‘required request’?

44. The Human Organ Transplants Act 1989 provides that Ministers may make regulations setting out the information about transplants that have been or are proposed to be carried out in Great Britain using organs removed from dead or living persons. The regulations can also specify to whom the information is to be provided. This power has been used to create the Human Organ Transplants (Supply of Information) Regulations 1989. These enable UK Transplant to maintain its databases, which are essential to ensuring equitable and safe allocation of organs for transplantation across the UK as a whole, for tracing patients in the event of a transmissible disease and assessing compliance with legislation. The power is carried forward in the Human Tissue Bill, and should be carried forward also under any new Scottish legislation, given the UK basis on which organs are shared.

Part 2: Transplantation of Organ and Tissue from the Living

Background

45. The increasingly severe shortage of cadaveric organs for transplantation has led to a growing emphasis on the donation of organs from the living. This is one of the main components of the Scottish Transplant Group's *Organ Donation Strategy for Scotland* and is also being encouraged by UK Transplant. It applies particularly to kidneys, where the waiting list is longest anyway, but parts of organs, such as liver or lungs, or small sections of the bowel, can now be transplanted as well.

46. The transplantation of whole organs from living people is dealt with in the Human Organ Transplants Act 1989, and Regulations made under that Act. The common law on consent as it relates to clinical interventions is relevant to the subject of transplantation of tissues from the living.

47. Because of their potential vulnerability, mature children should not be given any discretion about live donation. The new legislation would therefore include a provision that no-one under the age of 16 could, while alive, authorise the donation of one of their organs. The legislation would also provide that a parent or parents could not authorise the removal of an organ from a living child under the age of 16. (Tissue banking is considered further in Part 3 of this paper.)

48. The definition of 'organ' in section 7(2) the 1989 Act ('any part of the human body consisting of a structured arrangement of tissues which, if wholly removed, cannot be replicated by the body'), may require adjustment in view of the developments in transplantation of parts of organs, such as liver lobes. These would not seem to be covered by the 1989 Act because of the inclusion of the word 'wholly' in its definition of 'organs'.

49. Section 2 of the 1989 Act prohibits organs from being removed from a living person and transplanted into another person unless the donor and recipient are genetically related. If the donor is able to give valid consent and is genetically related, there is no legal requirement for independent scrutiny. The 1989 Act specifies the following relationships as a genetic relationship to the potential donor:

- his natural parents and children;
- his brothers and sisters of the whole or half blood;
- the brothers and sisters of the whole or half blood of either of his natural parents;
- the natural children of his brothers and sisters of the whole or half blood or of the brothers and sisters of the whole or half blood of either of his natural parents.

50. If the potential donor is not genetically related to the recipient, the donation of an organ cannot take place until approval has been obtained from the Unrelated Live Transplant Regulatory Authority (ULTRA). ULTRA is a cross-border public authority in terms of the Scotland Act 1998 (Cross-Border Public Authority) (Specification) Order 1998. Its constitution is set out in the Human Organ Transplants (Unrelated Persons) Regulations 1989 (SI 1989 No. 2480). Members of ULTRA scrutinise applications for live transplants to satisfy themselves that the parties are aware of the nature and risks of the procedure, that consent is being given freely without pressure being put on the donor, that no payment (other than re-imburement of expenses) is being made to the donor, and that the donor is aware that

he or she is entitled to withdraw consent at any time. Applications for approval for unrelated live transplants in Scotland are considered by ULTRA at present.

51. The legislation proposed for the rest of the UK is intended to embody 2 changes relating to the current functions of ULTRA. The independent scrutiny which is currently given to unrelated live transplants would be extended to cover *all* live transplants. It would also cease to exist as a separate body, with its extended functions being absorbed into those of the Inspectorate for Organs and Tissue for Human Use. These 2 issues are considered below.

52. The consultation paper *Human Bodies, Human Choices* suggests (paragraph 14.14) that in today's society, with a tendency to more dispersed families, the fact of an existing genetic relationship, as defined in the 1989 Act, cannot be assumed automatically to equate to a close personal relationship between potential donor and recipient. Equally, much closer relationships may exist between individuals, such as husband and wife, than between those defined by the Act as genetically related. The consultation paper goes on to argue (paragraph 14.16) that it is far harder to ensure that family members or others close to the potential donor, who also have an interest in the potential recipient, do not exert undue influence on the donor. Transplants between such relatives are not currently subject to any independent scrutiny, and there may be instances in which some protection would be desirable. The consultation on *Human Bodies, Human Choices* showed support for the proposition that all living transplantation should require independent oversight, with an end to the current distinction between related and unrelated donors. This will be reflected in the new legislation proposed for the rest of the UK.

53. Given that this protection will extend in principle to live donations in the rest of the UK, it would be difficult not to follow suit in Scotland. Most live donors in Scotland already receive independent medical review, so placing this on a statutory basis would in part confirm current good practice.

54. Live kidney donation could be increased by paired donation, which is when two potential pairings, hampered by blood group incompatibility, mutually benefit by kidney exchange between the pairings (for example, donor A, who is incompatible with recipient A, gives to recipient B, and donor B gives to recipient A). At present, this type of arrangement would not be approved by ULTRA. A further possibility is 'altruistic' donation, when a member of the public expresses a wish to donate a kidney to the national pool of potential recipients. Again, this would not be approved by ULTRA at present.

55. As noted in paragraph 51, ULTRA's functions in the rest of the UK would be absorbed by the Inspectorate for Organs and Tissue for Human Use. This development gives rise to 3 possible options for Scotland:

- the creation of a separate body for Scotland; or
- the retention of ULTRA, the existing body, for Scotland; or
- the extension to Scotland of this element of the functions of the Inspectorate for Organs and Tissue for Human Use.

56. In view of the fact that only 40 living transplants (related and unrelated) took place in Scotland in 2003, there would seem to be little justification for setting up a separate new body, or retaining ULTRA in its present form, to scrutinise live transplants in Scotland. There would also be issues about jurisdiction, since in a number of cases the live donor might be

resident in another part of the UK. It would therefore seem preferable to extend to Scotland this aspect of the functions of the Inspectorate of Organs and Tissue for Human Use.

57. As noted in paragraph 29, the Human Organ Transplants Act 1989 contains penalties to prevent trafficking in organs. Those sanctions were originally introduced because of a case involving the sale of kidneys from living donors, and should therefore continue to apply to all types of live donation.

Question 16:

Should the scrutiny of live transplants in Scotland be extended to cover cases where the donor and recipient are genetically related? If so, would this remove the current need for related donors to prove their relationship by genetic blood testing? Would it be possible not to make such a change in Scotland if it is being implemented in the rest of the UK?

Should role of Inspectorate for rest of UK be extended to Scotland for these purposes, or should a separate body be created in Scotland to take on this responsibility?

Should paired and altruistic live donation be possible in Scotland?

58. Tissue donation from the living is quite different from live organ donation. Bone and other tissue is often regarded as a waste product, in that it would normally be discarded. In order for it to be used, the appropriate authorisation must be obtained from the person concerned. A Working Group of the Scottish Medical and Scientific Advisory Committee has been developing a standard authorisation form and patient information leaflets on the use of 'surplus' tissue. The Department will scrutinise this work carefully to ensure the proposals are broadly consistent with the arrangements proposed for such tissue in the Human Tissue Bill, and that full account is taken of the relevant points raised in the debates on the Bill in the Westminster Parliament. There will be widespread consultation on the form and leaflets, particularly so that the views of the public and organisations representing the interests of patients can be taken fully into account.

Part 3: Tissue Banking

59. The Human Tissue Bill indicates that the Inspectorate of Organs and Tissue for Human Use would be responsible for licensing tissue banks which store and process tissue for human use. Tissue banks in the UK are currently accredited by the Medicines and Healthcare products Regulatory Authority (MHRA) on a non-statutory basis.

60. Again, the effect of this development on Scottish arrangements needs to be considered. The Scottish National Blood Transfusion Service is the preferred provider of tissue banking in Scotland. These arrangements are at present purely administrative, and rest on a Code of Practice for Tissue Banking issued in 2001 by the Health Departments.

61. The European Commission published proposals for a Directive on the Quality and Safety of Tissues and Cells for Human Transplantation in June 2002. The Directive is intended to ensure the safety and quality of human tissues and cells intended for or used in all human applications by introducing a harmonised regulatory framework across Europe. It would require a competent authority in each Member State to inspect and accredit establishments carrying out tissue banking activities. The voluntary scheme currently operated by MHRA will therefore be placed on a statutory basis. Arrangements in Scotland will take account of the way this development is implemented in the rest of the UK.

62. UKT provides the cornea transplant service that includes funding to eye banks in Bristol and Manchester. These banks supply the majority of corneas to NHS patients undergoing transplantation in the UK. The banks store tissue that has been donated by deceased people across the UK. Organising the service on a UK-wide basis ensures a constant supply of corneas is available.