HUMAN TISSUE (SCOTLAND) BILL

POLICY MEMORANDUM

INTRODUCTION

1. This document relates to the Human Tissue (Scotland) Bill introduced in the Scottish Parliament on 3 June 2005. It has been prepared by the Scottish Executive to satisfy Rule 9.3.3(c) of the Parliament’s Standing Orders. The contents are entirely the responsibility of the Scottish Executive and have not been endorsed by the Parliament. Explanatory Notes and other accompanying documents are published separately as SP Bill 42–EN.

POLICY OBJECTIVES OF THE BILL - GENERAL

Introduction

2. The Bill covers 3 main issues: organ and tissue donation and transplantation; hospital post-mortem examinations; and the Anatomy Act 1984.

3. The policy intention is to repeal for Scotland the Human Tissue Act 1961 (the “1961 Act”) and replace it with legislation containing distinct provisions appropriate to Scotland relating to organ donation and transplantation from deceased donors, and to hospital post-mortem examinations. Furthermore, the intention is to amend for Scotland and incorporate in the new legislation the provisions in the Human Organ Transplants Act 1989 (the “1989 Act”) relating to living donors. The Anatomy Act 1984 (the “1984 Act) will also be amended as respects Scotland to broaden the definition of ‘anatomical examination’, address public concerns about use of bodies and body parts in public displays, and to allow the post of HM Inspector of Anatomy for Scotland to continue following changes made by the Human Tissue Act 2004 (the “2004 Act”).

Policy Objectives - Background

4. The provisions of the Bill relating to organ and tissue donation and transplantation take account of 3 key factors: the Executive’s policy on organ donation and transplantation as set out in the Organ Donation Strategy for Scotland devised by its expert advisory group, the Scottish Transplant Group; the scrutiny of the existing legislation, the 1961 Act, which covers both transplantation and hospital post-mortem examinations, undertaken by both the Scottish Transplant Group and the Review Group on Retention of Organs at Post-Mortem; and the

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1 Scottish Executive, Organ Donation Strategy for Scotland (2002)  
legislation which has been developed for the rest of the UK, as set out in the 2004 Act which repeals and replaces the 1961, 1984 and 1989 Acts for the rest of the UK.

5. The Organ Donation Strategy was published on a consultative basis in July 2002. It drew attention to a number of problems with the 1961 Act. In particular, this legislation covers both transplantation and hospital post-mortem examinations and this has helped to create confusion in the public mind between the two issues. For example, families affected in the past by organ retention following a hospital post-mortem examination have indicated strong support for organ donation and transplantation, while expressing corresponding concern at the confusion of the two issues. The Strategy, therefore, called for the 1961 Act to be replaced by separate legislation governing organ and tissue donation on the one hand, and retention of organs and tissue at post-mortem examination on the other. The same recommendation was made by the Review Group on Retention of Organs at Post-Mortem.

6. Another concern surrounding the 1961 Act raised by the Scottish Transplant Group was that it fails to acknowledge the reality of many contemporary relationships, which may for example, not involve marriage, or may be of the same sex. The Act currently provides that the person lawfully in charge of the body may authorise the removal of any part of the body for therapeutic purposes if, having made such reasonable inquiry 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. The use of the term ‘spouse’ is both dated and restrictive, and legislation which currently attaches the same degree of weight to the views of the surviving spouse to those of even the most distant relative is difficult to justify. Furthermore, the role of the ‘person lawfully in possession of the body’ is unclear.

7. The difficulties of interpreting the 1961 Act’s provisions in the context of organ and tissue donation and transplantation have meant that hospitals have had problems in determining a proper role for the surviving spouse and relatives. While 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 to ensure that there are no medical reasons why donation would be inadvisable, the way in which the transplant community addresses the issue has tended to suggest that the decision whether to proceed with retrieval rests with the relatives. In strict legal terms, this goes beyond the provisions of the 1961 Act. It also opens up the possibility of the deceased’s wishes, as expressed by carrying a donor card or putting their name on the NHS Organ Donor Register, being vetoed by the relatives.

8. The Organ Donation Strategy therefore made a number of recommendations for new legislation. In particular it called for the system of ‘opting-in’ to be strengthened by placing the emphasis, in discussions with relatives, on determining what wishes, if any, the deceased might have expressed. The carrying of an organ donor card and/or registering on the NHS Organ Donor Register should be regarded as types of advance directive, so that the wishes of the deceased should be fulfilled wherever possible. ‘Relatives’ should also be understood as meaning those who had been closest in life to the potential donor and therefore those who were most likely to have known his or her views on the subject in the absence of any tangible expression of them.
TRANSPLANTATION ETC.

Policy Objectives - Specifics

Authorisation

9. The Executive’s policy intention is that the new legislation for Scotland should be firmly rooted in the positive attitudes towards organ and tissue donation and transplantation held by 90% of the population. The policy is also to apply the concept of ‘authorisation’, as developed by the Review Group on Retention of Organs at Post-Mortem (described later in this document – see paragraphs 40 and 41) to the transplantation context in order to recognise that this is an active decision taken by someone in a position of control. Part 1 of the Bill is couched in terms of ‘body parts’, rather than ‘organs’ and ‘tissue’, so that it takes account of future technical developments affecting the range of body parts which can be transplanted.

10. The Bill’s intention is that where an individual carries an organ donor card and/or adds their name to the NHS Organ Donor Register, those wishes are given effect and this will be regarded as authorisation. Recent research indicates that many of those who carry a donor card 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. 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 some parts of the country relatives refuse to agree to organ donation in up to 78% of cases where the views of the deceased are not known. 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% now. The principle of autonomy would mean that the deceased person’s wishes should be respected, whether these had been expressed in writing or verbally. This is consistent with the fundamental principle of consent which will apply in the rest of the UK.

11. The Bill provides for self-authorisation to be in writing, or it can be expressed verbally. Written authorisation by the person him or herself need not be signed, so as to allow for online registration on the NHS Organ Donor Register maintained by UK Transplant (UKT). This will require stringent administrative safeguards to ensure the authenticity of such registrations. The Executive will work with UKT and the other Health Departments on developing these safeguards.

12. Where the deceased has not left any specific expression of wishes, the policy intention is that an approach should be made to the ‘nearest relative’: defined by means of a hierarchy similar to that in the Mental Health (Care and Treatment)(Scotland) Act 2003. Authorisation should be obtained from the person whose relationship to the deceased comes highest in the hierarchy, as the person most likely to have been closest to the deceased in life and therefore most likely to have been aware of the deceased’s general attitudes towards such issues. That hierarchy includes registered civil partners as well as unmarried partners and partners of the same sex.

13. The policy intention is that the principle of respecting the deceased’s wishes should not allow the family a right of veto. The number of cases where there is likely to be any conflict

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2 UK Transplant, Potential Donor Audit (Ongoing)
between the wishes of the individual and the wishes of the family is believed to be small, however, as the evidence indicates that most families accept that organ and tissue donation should go ahead when provided with evidence that that was the deceased’s wish. The Executive’s advertising and publicity campaigns will continue to promote the message that people should not simply carry a donor card or put their name on the Register, but also should let their nearest relatives know their wishes, so that the relatives do not have to confront the issue for the first time in the initial stages of bereavement, and have been made aware of the deceased’s wishes at first hand.

14. In line with current arrangements, the policy intention is that where organs and tissue cannot be used for the primary purpose of transplantation, it should be possible to authorise their use for purposes of research, as well as for teaching and audit. The Bill also provides for authorisation of the use of organs or tissue solely for research purposes, as is permissible at present under the 1961 Act. The arrangements set out in the Bill reflect the fact that this is often a two-stage process. The individual in life makes broad decisions about organ donation. After death, the relatives will be approached by a transplant co-ordinator to discuss these wishes in more detail, or to deal with any specific issues about which the individual recorded no wishes.

Transplants from living donors

15. The Bill includes repeal for Scotland of the 1989 Act, which currently regulates organ donation and transplantation from the living, and replace it with provisions consistent with those being made for the rest of the UK as set out in the 2004 Act.

16. In broad terms, the 1989 Act is designed to prevent the making or receiving of payments for organs for transplantation, or the placing of adverts inviting people to supply organs for transplantation in exchange for payment. The 1989 Act also provides for a system of scrutiny of live transplants between people who are unrelated genetically, to ensure that the parties are aware of the nature and risks of the procedure, that agreement is being given freely without pressure being put on the donor, that no payment (other than re-imbursement of expenses) is being made to the donor, and that the donor is aware that he or she is entitled to withdraw from the process at any time.

17. The policy aim is to ensure that the position in Scotland remains consistent with that for the rest of the UK. The Bill therefore makes two main changes. The system of independent scrutiny is being extended to cover the transplantation of parts of organs, to take account of new developments such as the establishment of living donor liver transplant programmes. It will also cover all live transplants, whether or not the potential donor and recipient are related, in order to provide independent scrutiny in every case. The Bill includes, inter alia, protection for the position of children by providing that it should not be possible to remove an organ from a living child under the age of 16 for purposes of transplantation, or to remove tissue from such child, other than regenerative tissue such as bone marrow. For Scotland, scrutiny of living donation is likely to be undertaken by the Human Tissue Authority established by the Human Tissue Act 2004, to ensure consistency of approach across the UK.
Penalties

18. There are penalty provisions for breaching the provisions of the 1989 Act. The policy is to carry forward penalty provisions for breaching provisions relating to transplants involving living donors in the Bill, with penalty levels revised to be consistent with the penalty provisions which will apply in the rest of the UK.

19. The policy intention is also to have penalties for breaching provisions relating to transplantation from deceased donors. The consultation paper had originally proposed that it would be inappropriate to apply any penalties in the context of transplantation of organs from the dead because the process has never given any cause for public concern and because of the existence of a range of agencies with responsibility for oversight of the various transplantation programmes. This approach was supported by 71% of those who responded. The Executive, however, has decided that in order to emphasise the importance attached to making sure that the individual’s wishes should be fulfilled there is a need to make provision for penalties in this context. The range of authorisation options is now more varied than proposed in the consultation paper and it is considered that would be inconsistent to safeguard that very similar range of authorisation intentions in the hospital post-mortem examination context but not in the context of transplantation. This is also consistent with the position under the Human Tissue Act 2004 and the penalty provisions have been aligned with its provisions.

EU Directive on the Safety of Tissue and Cells

20. The Bill also takes account of the provisions of the EU ‘Tissues and Cells Directive’ (Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells). This replaces the present voluntary Code of Practice for Tissue Banks\(^3\), issued by the UK Health Departments in 2001, with a statutory system of regulation. The Directive requires transposition into UK law by April 2006. In the rest of the UK, the Human Tissue Authority will become the single ‘competent authority’ under the Directive, with responsibility for enforcing all relevant safety and quality requirements. Scotland has one therapeutic tissue bank, operated by the Scottish National Blood Transfusion Service as its preferred provider (NHS Health Department Letter(2001)27), and the intention is that the Human Tissue Authority should undertake the regulation of this tissue bank on behalf of the Scottish Ministers in fulfilment of the requirements of the Directive.

Alternative Approaches

‘Presumed Consent’

21. In developing its approach to new legislation on organ donation and transplantation, the Executive was aware of the support which exists for a move towards a system of ‘opting out’, or ‘presumed consent’, based on the presumption that organs and tissue can be retrieved after death for transplantation provided the dead person had not registered an objection.

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\(^3\) UK Health Departments, A Code of Practice for Tissue Banks – Providing Tissues of Human Origin for Therapeutic Purposes (February 2001)
22. The Executive has therefore looked very carefully at the arguments put forward by those in favour of presumed consent. The main aims of that system are to increase the number of donor organs, to honour the deceased person’s wishes and to consult the relatives. The Executive agrees with each of those aims, and the Bill addresses them all. Respecting the wishes of the deceased forms the cornerstone of the proposals, which are based on treating donor cards or registering on the NHS Organ Donor Register as forms of authorisation of the use of organs or tissue for transplantation after death. A key element in the new arrangements stressed by those in favour of presumed consent is the way that relatives are approached. The Executive fully accepts that the process has to be made as easy for them as it can be in such circumstances. For most people, that is achieved through knowing that allowing organ donation to go ahead would fulfil their loved one’s wishes. The Executive also thinks that the idea of offering organs as a gift is important in helping people to derive some solace from their own loss, as well as in maintaining public confidence and support for transplantation at its present 90% level. A further consideration is 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.

23. A further factor which the Executive has taken into account is that the arrangements for allocating organs for transplantation operate across the whole of the UK. The Executive believes that the fundamental principle on which organ donation rests should therefore be consistent across the UK. The 2004 Act is based on the same fundamental principle of respecting the express wishes of the individual.

Surplus or residual tissue

24. The Bill contains no provisions in respect of surplus or residual tissue. Tissue donation from the living is a different matter from living organ donation. Bone and other tissue are usually regarded as waste products, in that they would normally be discarded from an operation or a diagnostic investigation such as a biopsy. Provisions relating to surplus or residual tissue appear in the Human Tissue Act 2004. The Executive’s policy, however, is that the arrangements for the authorisation of the use of surplus tissue can be dealt with satisfactorily by guidance and an appropriate authorisation form. It sees no need to introduce measures in this area more stringent than those which apply to the consent a living person gives to the carrying out of an operation. These proposals were included in the consultation and no representations have been received objecting to this approach. The guidance will, however, be consistent with that issued by the Human Tissue Authority under the 2004 Act, since obtaining and using human tissue for research purposes should be neither easier nor more difficult in Scotland than other parts of the UK. There is the further safeguard that all research involving human tissue will always require the approval of a Research Ethics Committee.

Consultation

25. These provisions of the Bill are based on the recommendations of the Scottish Transplant Group, which includes representatives of the public as well as the voluntary sector. These were published as part of the Group’s Organ Donation Strategy for Scotland on a consultative basis in July 2002 and the responses indicated general support for the Group’s recommendations on the basis for new legislation in Scotland.
26. A further public consultation specifically on the legislation relating to organ and tissue donation and transplantation ended in June 2004. Responses were received from a wide range of people and organisations in the public, private and voluntary sectors. There was unanimous support for a revision of the current legislation and the great majority of respondents agreed that no further proof of wishes should be needed than carrying a donor card or registering on the NHS Organ Donor Register. A report of the independent analyses of the responses to the consultation was published on 28 February 2005, with a covering letter from the Minister for Health & Community Care.

Effects On Equal Opportunities, Human Rights, Island Communities, Local Government, Sustainable Development, Etc

Equal Opportunities

27. The provisions of the Bill are not discriminatory on the basis of gender, race, disability, marital status, religion or sexual orientation. The new legislation will ensure that objections to transplantation on religious grounds would be respected, and that no discriminatory conditions could be imposed on authorisation for purposes of transplantation.

Human Rights

28. The Executive is satisfied that the provisions of the Bill are compatible with the European Convention on Human Rights.

Island Communities

29. These provisions of the Bill apply equally to all communities in Scotland. Place of residence is not a factor in relation to access to transplantation programmes.

Local Government

30. The Executive is satisfied that the Bill will not have an impact on local government. The lead on implementing the legislation will fall to Health Boards with central support and guidance provided by the Executive.

Sustainable Development

31. Meeting the Needs... describes how building a national effort to improve health, reducing inequalities in health and making the NHS a ‘national health service’ and not a ‘national illness service’, is an integral part of sustainable development. The Executive has made clear that efforts to promote health, alongside programmes on social justice, crime and transport, are central to sustainable development.

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5 Scottish Executive, Legislation Relating to Organ and Tissue Donation and Transplantation: Analysis of Consultation Responses. (February 2005)
6 Scottish Executive, Meeting the Needs... Priorities, Actions and Targets for sustainable development in Scotland (2002)
HOSPITAL POST-MORTEM EXAMINATIONS

Policy Objectives - Background

32. The need to amend the law relating to hospital post-mortem examinations stems from the considerable distress caused to families throughout Scotland after the publication in spring 2000 of the Interim Report from the public inquiry into paediatric cardiac surgery at Bristol Royal Infirmary\textsuperscript{7}. It disclosed that considerable numbers of children's hearts had been retained following post-mortem examinations, both hospital and those instructed by the coroner, without the knowledge or agreement of the parents. In the wake of Bristol, there was a sequence of further revelations, in particular from the inquiry into practices at Alder Hey Children’s Hospital, Liverpool, which compounded that distress.

33. From the inquiries made by families of what were then NHS Trusts in Scotland, it became clear that past practice here had been similar to that in England. The signature on a hospital post-mortem examination consent form had been taken as sufficient warrant to allow the retention of organs, tissue blocks and slides following the examination. In many cases, no explanation had been offered to the families as to what was involved in the post-mortem examination, as it was thought this would compound the distress they were already suffering at the loss of their child. The clinicians concerned believed that they were acting in the best interests of the families themselves, and for the wider public good, and also believed that they had satisfied the provisions of the 1961 Act.

34. The majority of the families affected with whom the Executive has been in contact have made clear that they did not necessarily object to the examination itself, or to the retention of organs for diagnosis or research purposes. Their distress was caused by the fact that they were not involved in the decisions about what should happen to their child after death. Many parents clearly feel the need to protect their child after death and for them, past post-mortem practice was seen as a betrayal of that protective role. Some families wished to have organs and tissue blocks and slides returned to them so that they could arrange for them to be disposed of in a way which the family considered fitting. For most, this meant the holding of another funeral.

35. Against this background, the Executive set up in September 2000 an independent Review Group on the Retention of Organs at Post-Mortem, with a remit to investigate past practice in Scotland and to make recommendations about the changes needed to the underlying legislation to make sure that such a situation could never happen again. The present Bill therefore fulfils a commitment to changing the law on hospital post-mortem examinations which was first given in the autumn of 2000. A great deal of administrative work has been done in the interim to help tackle the problems of the past.

36. On the issue of post-mortems involving adults, publication of the Isaacs Report\textsuperscript{8} in 2003 showed that retention of organs at post-mortem examination without the knowledge of the family

\textsuperscript{7}Bristol Royal Infirmary Inquiry, *The Inquiry in the Management of Care of Children Receiving Complex Heart Surgery at the Bristol Royal Infirmary. Interim Report.* (May 2000)

had occurred in cases involving adults as well as children and could, in particular instances, generate as much distress as the cases involving children.

37. The Review Group’s work clarified the general principles which should underpin the new legislation in Scotland. One of its main aims had to be to place the sense of control in the hands of the parents when there was any question of a hospital post-mortem examination on a baby or young child. In the case of adults, the fundamental aim would be to enshrine in the legislation a requirement to give effect to any prior notification of the competently-expressed wishes of the deceased and to ensure that people’s decisions about what should happen to their own body after death are respected.

38. The Group also stressed that the hospital post-mortem examination should properly be regarded as part of the continuum of care provided by NHSScotland, a continuum which extends beyond the death of the patient. New legislation should therefore be aimed at restoring public confidence in the post-mortem examination. The Group suggested that the new legislation should be restricted as far as possible to setting a framework of key principles, since the problems with the 1961 Act show that primary legislation can rapidly become out of date, especially in areas where great sensitivity and a responsiveness to the changing views of society are required. The Review Group concluded that the 1961 Act was fundamentally flawed, and recommended that it should be repealed for Scotland in respect of hospital post-mortem examinations and replaced by legislation containing separate provisions for transplantation and for hospital post-mortem examinations.

39. The provisions of the Bill on hospital post-mortem examinations are intended to give expression to the principles set out by the Review Group. The approach of including the minimum in primary legislation has been assisted by the fact that NHS Quality Improvement Scotland very quickly took up a recommendation from the preliminary report of the Review Group (February 2001)\(^9\) and developed clinical standards covering the hospital post-mortem examination process. These standards are mandatory on all NHS hospitals which undertake post-mortem examinations. Details of the first NHS Quality Improvement Scotland reviews of its hospital post-mortem examination standards are given in the national overview and local reports published on 16 February 2005\(^10\).

**Policy Objectives - Specifics**

**Authorisation**

40. The policy intention is to follow the recommendation of the Review Group that the new legislation should be based on the concept of ‘authorisation’. This idea was prompted by the consideration that the idea of ‘consent’ was inappropriate, and this was particularly clear in the context of a post-mortem examination on a child. The rationale behind the concept of ‘consent’

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was based on doing what was in the best interests of the child, but in the post-mortem context the child could no longer be considered as having any interests. The Review Group therefore looked for an alternative concept and chose ‘authorisation’, a term based on a recognition of the intimate bond between parents and children, the privacy of the family unit and the right to prevent interference by third parties with the intimacy of the family relationship. The use of the term ‘authorisation’ recognises the role which parents must be given in making decisions about the way their children should be dealt with after death, as in life. Granting ‘authorisation’ strongly suggests an active decision taken by someone in a recognised position of control, whereas ‘consent’ implies a passive acceptance of something being proposed by someone else.

41. A further consideration is extremely significant in the post-mortem examination context. ‘Consent’, to be valid in law, is generally expected to follow the provision of information, but many people, parents in particular, do not want to be given details about organ removal, retention and use. Since ‘authorisation’ is based on a power to make decisions, it can be given even if no information has been provided about what is being authorised, as long as the person authorising understands what may be the effect of giving that authorisation.

42. The Bill sets out the purposes for which a hospital post-mortem examination may be undertaken, the material which may be retained as a result of the examination and the purposes for which it may be used. The policy intention should be that the examination itself and the purposes for which retained material may be used must be authorised. An adult with capacity may while alive authorise the carrying out of the post-mortem examination, as may mature children, by which should be understood children between the ages of 12 and 16 who are considered capable of understanding the significance of their decisions. Both adults and mature children should also be able to nominate someone to take the decision whether or not to authorise a hospital post-mortem examination. Failing either of these, the Bill provides for authorisation to be given by the deceased’s ‘nearest relative’ and provides a hierarchy of relatives which should enable the identification of the person who was closest to the deceased in life. In the case of children under 12, or between the ages of 12 and 16 who left no wishes, authorisation must be given by the person or persons having parental rights or responsibilities in respect of the child.

Standard Authorisation Forms

43. The policy is that this framework of authorisation should be underpinned by standard authorisation forms and information leaflets which have been developed for use across Scotland. This is in response to the need for uniformity of approach highlighted by both families and health professionals. Two forms have been developed, one for a hospital post-mortem examination on an adult, the other for an examination on a child. Considerable thought has been given to making sure that the form sets out in a manageable way all the authorisation options which should be available, while at the same time being capable of use without adding unnecessarily to the family’s distress. Drawing on experience of the problems of the past, the forms make a clear distinction between retention of tissue blocks and slides, the creation of which is an integral part of the post-mortem examination and which should form part of the deceased person’s medical record, and organs, which should only be retained in exceptional circumstances, and which therefore requires separate and specific authorisation. This also reflects the much greater emotional significance of organs. In order to ensure that these are the
only forms which can be used, the policy is that their content will be specified in Regulations to be made under the Bill.

Examinations Instructed by the Procurator Fiscal

44. In fulfilment of a recommendation of the Review Group, the Executive acknowledges the importance of allowing families who have had a post-mortem examination instructed by the Procurator Fiscal the opportunity of authorising the use for purposes such as education and research any organs or tissue retained as a result of the examination, provided these are no longer required for the Fiscal’s purposes. The Bill therefore provides that tissue samples retained should become part of the deceased person’s medical record once the Fiscal has indicated that they are no longer required for his or her purposes, and can be used for diagnostic purposes and audit without the need for authorisation from the nearest relative, and for research, education and training provided those uses have been properly authorised. The Bill also allows for the possibility that whole organs no longer needed for the Fiscal’s purposes could be used for education, training or research provided proper authorisation has been given for these uses. For the fiscal setting, the Bill extends the hierarchy of relatives to include someone who had a long-standing professional relationship with the deceased person.

45. For existing holdings of tissue samples retained from an examination instructed by the Fiscal before the Act comes into force, the Bill allows for the retention of tissue samples for education, training and research purposes without the need for further authorisation. For existing holdings of organs retained from an examination instructed by the Fiscal before the Act comes into force, the Bill provides that these can be retained for the purposes of that research, or for education, training or subsequently approved research purposes if authorised in the appropriate manner, and of the research use if the organ is in addition approved by the Research Ethics Committee.

46. The Executive believes these provisions reconcile the needs of individual families and those of society in a way that is consistent with the general approach to authorisation of hospital post-mortem examinations. The provisions about existing holdings build on the present arrangements, which were devised by the family support groups with which the Review Group dealt, and which were formalised from 18 April. When they come into force, the provisions in the legislation will supersede this administrative arrangement.

Penalties

47. One of the main criticisms of the 1961 Act was that it contained no penalties for non-compliance with the regime it set out for hospital post-mortem examinations. The Bill addresses that criticism directly by including penalty provisions. These will be triggered if a hospital post-mortem examination is carried out without authorisation, or if the detailed terms of the authorisation are not respected. The level of penalties equates to those set out in the 2004 Act for the rest of the UK.
Alternative Approaches

Examinations Instructed by the Procurator Fiscal

48. The Executive is aware of arguments that the new legislation should extend to the post-mortem examinations instructed by the Procurator Fiscal, on the grounds that many of those most distressed by past practice had been those whose child had been the subject of a medico-legal post-mortem examination, and who found it difficult to accept that they had no say in the decision whether or not such an examination should be undertaken. The Executive considers it essential, however, that the Procurator Fiscal should continue to be able to instruct a medico-legal post-mortem examination in pursuance of his duty to investigate all sudden, suspicious or unexplained deaths. A system of authorisation is incompatible with that responsibility, which relates to the administration of justice. The Crown Office and Procurator Fiscal Service is aware, however, of the importance this places on good communication with the family, especially the need to inform them whether any organs have been retained as a result of the post-mortem examination. The new arrangements for the authorisation of educational or research use of organs or tissue samples no longer needed for the Fiscal’s purposes require a process of clear notification by the Fiscal that his or her purposes are complete, and this is provided for in the Bill. The Bill does not affect in any way the Fiscal’s entitlement to retain organs or tissue samples for as long as these are required for his or her purposes.

Inspection and Regulation

49. The Executive has also considered whether the framework of authorisation provided for in the Bill should be overseen by a system of inspection and regulation of hospital post-mortem examinations such as is provided in the 2004 Act, which sets up a Human Tissue Authority and an Inspectorate of Anatomy and Pathology. This is not considered necessary, in part in recognition of the deterrent effect of the penalty provisions, but largely because of the role of NHS Quality Improvement Scotland in reviewing performance against its hospital post-mortem examination standards. The standards have been developed with strong input from family support groups, and are mandatory on those in the NHS providing this service. In addition, the reviews against standards include strong representation from those who are not health professionals. A local report is published of performance against the standards, as is a national overview which draws together common themes from the local reports. The Bill nevertheless secures that the Scottish Ministers could ask the Human Tissue Authority to exercise any of its functions in Scotland on their behalf, including those of inspection and regulation if it were thought necessary to do so.

Authorisation by one parent

50. In the case of the authorisation of a hospital post-mortem examination on a child, there was no clear consensus on the circumstances in which one parent’s views on authorisation should be allowed to prevail. The Review Group too had been unable to reach a decision on this point, which indicates the difficult ethical and social issues involved. The Bill provides that one parent should be able to authorise the hospital post-mortem examination since, in the majority of cases, both parents should be present and may be expected to agree on whether or not to give their authorisation. This is recognised in the authorisation form, which should allow both parents to sign should they so wish. Allowing one parent to authorise the examination is consistent with the approach adopted in the 2004 Act. There should be a smaller number of cases where the hospital is dealing with only one parent, and if that parent wishes to authorise a
hospital post-mortem examination, it seems reasonable that those wishes should not be thwarted by a parent who appears to have been taking no interest in the child while alive, or because the other parent cannot, for whatever reason, be contacted at the time. There will undoubtedly be cases where parents disagree and, while the legislation would allow a post-mortem examination to proceed on the authorisation of one parent, the hospital is not obliged to do so and should be able to take a pragmatic decision based on the strength of opposition being expressed by the dissenting parent. More detailed guidance will be issued to deal with the variety of circumstances which could arise and that would be developed in conjunction with the other UK Health Departments and the Human Tissue Authority to ensure consistency of approach to this very sensitive issue.

Post-Mortem Examinations Without Authorisation

51. The consultation asked for views on whether there were any circumstances under which there might be sufficient public interest to warrant undertaking a hospital post-mortem examination without authorisation. A majority of those who commented felt that this could be justified in circumstances of a public health risk from an unknown disease, where a quick diagnosis was considered necessary. The Executive considers, however, that this contingency is already sufficiently provided for by the power of the Fiscal to instruct a post-mortem examination. If the doctor cannot write a death certificate because the cause of death is unknown, the case has to follow the Fiscal route. Any other exemption runs a very serious risk of undermining the whole concept of authorisation by returning to a system under which families felt they could be deprived of control by the medical profession over what was happening to their loved one after death.

Consultation

52. The Review Group’s second report, published in November 2001, contained its recommendations on the legislation. There was extensive consultation on that report and the responses showed broad support for the approach proposed by the Review Group.


54. A further consultation on the legislation relating to hospital post-mortem examinations ended in February 200411. The responses indicated general support for the proposals. Reports of the independent analyses of the consultation responses were published on 28 February 2005, with a covering letter from the Minister for Health & Community Care12.

12 Scottish Executive, Legislation Relating to Hospital Post-Mortem Examinations: Analysis of Consultation Responses. (February 2005)
Effects On Equal Opportunities, Human Rights, Island Communities, Local Government, Sustainable Development, Etc

Equal Opportunities

55. The provisions of the Bill are not discriminatory on the basis of gender, race, disability, marital status, religion or sexual orientation. The new legislation will ensure that objections to hospital post-mortem examinations on religious grounds would be respected.

Human Rights

56. The Executive is satisfied that the provisions of the Bill are compatible with the European Convention on Human Rights. The concept of authorisation was developed from consideration of the Human Rights article which deals with the privacy of the family. There is a particular need in the hospital post-mortem examination context to be sensitive to the religious views of the family.

Island Communities

57. These provisions of the Bill apply equally to all communities in Scotland.

Local Government

58. The Executive is satisfied that the Bill will not have an impact on local government. The lead on implementing the legislation will fall to Health Boards with central support and guidance provided by the Executive.

Sustainable Development

59. Meeting the Needs... describes how building a national effort to improve health, reducing inequalities in health and making the NHS a ‘national health service’ and not a ‘national illness service’, is an integral part of sustainable development. The Executive has made clear that efforts to promote health, alongside programmes on social justice, crime and transport, are central to sustainable development.

AMENDMENT OF THE ANATOMY ACT 1984

Introduction

60. The Anatomy Act 1984 (the “1984 Act”) and the Anatomy Regulations 1988 set out a regulatory framework authorising anatomical examinations on corpses for the purposes of teaching or studying or researching into morphology. In addition the 1961 Act permits the removal of body parts from a corpse for the purposes of medical education or research as well as therapeutic purposes (organ donation) where a person has made a request that his body be used for those purposes and where a person is in lawful possession of the body.

61. The Anatomy Regulations prescribe additional requirements for the records which must be kept for anatomical examinations and the retention of anatomical specimens. They provide that a person who has been granted a licence to carry out anatomical examinations under the 1984 Act must compile records in relation to each anatomical specimen which is in his or her
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possession. The Regulations also make provision as to the disposal of bodies following anatomical examination and preservation of the body prior to examination.

62. The key features of the 1984 Act are:

- A regulatory framework in the shape of Her Majesty’s Inspector of Anatomy (HMIA);
- Anatomical examination can only be carried out on licensed premises and by a person who is licensed to carry it out. Licences are granted by Scottish Ministers;
- The requirement for a request from an adult that his/her body should be used after death for anatomical examination;
- Authority to examine expires after 3 years after the date of death;
- Body parts may be retained for separate study with the permission of the person bequeathing their body and the agreement of the relatives;
- Body parts can only be used for anatomical examination, which includes dissection and visual examination;
- Full records of bodies and all anatomical specimens, their use and disposal must be retained for at least 5 years from the date of disposal of the body.

63. Under section 9 of the 1984 Act there are powers for Scottish Ministers to appoint their own HMIA. However, it has been customary for some time for the same HMIA to be appointed for England and Wales and Scotland, but with the title in Scotland of HM Inspector of Anatomy for Scotland.

64. There are currently eight licensed Departments of Anatomy in Scotland, including five medical schools.

65. The Executive received representations about perceived shortcomings in the 1984 Act. These focussed on constraints which while allowing anatomical examination do not permit training in surgical techniques, surgical reconstruction or insertion of implants. While graduate surgical trainees and students can dissect a corpse, they cannot practise surgical procedures that fall outside the scope of anatomical examination as it is currently defined in the 1984 Act. For example in relation to orthopaedic surgery, the 1984 Act allows the surgical exposure of the hip joint but precludes any further steps in the procedure, for example implantation of hip joint replacement. Moreover, it is considered important to develop and research new techniques and procedures to ensure that bodies which are donated in this way are preserved in suitable conditions to allow every facet of surgical training to be practised and honed.

66. Another deficiency in the current legislation was identified when there was recent controversy over the public display of freeze dried corpses which had been previously dissected outwith the UK and for which no licence to carry out the display was required. HMIA has no power to inspect unlicensed premises where it is suspected that an offence under the 1984 Act may be taking place.
67. In addition, the Department of Health is planning to repeal the Anatomy Act 1984 and the Human Tissue Act 1961 for the rest of the UK and replace under the terms of the Human Tissue Act 2004. The Human Tissue Authority which has been set up under the Act will include an inspectorate which would incorporate, broadly speaking, the functions of the HMIA as set out in the 1984 Act. Although the 1984 Act can continue to remain in place for Scotland, the new inspectorial structure in England and Wales could impact on HMIA arrangements for Scotland.

Policy Objectives

68. The policy intention falls into three principal areas. The first is that the definition of “anatomical examination” in the 1984 Act should be amended to allow for the practice of surgical reconstruction to be carried out on bodies and body parts and also the practice of removing whole organs or parts of organs by healthcare professionals.

69. The need for a change in the legislation was raised first by the Royal College of Surgeons of Edinburgh. Surgeons practice anatomical examination to learn about the structure of the body. However, training in medical procedures should also be included. The 1984 Act, as it stands, only allows for the dissection of a donated cadaver and not the practice of medical techniques. For example, it would be possible under the existing Act for students to surgically expose a hip joint and the surrounding area, which would be the first step in carrying out a hip replacement, but not to carry out further steps in the procedure such as the preparation of the bone, the removal of the joint and the implantation of an artificial replacement joint because they would not fall into the current definition of anatomical examination. The Royal College considered that allowing training in surgical procedures to be carried out on bodies and body parts would greatly enhance the training of all medical professionals, particularly surgeons.

70. The policy intention, therefore, is to extend the scope of the 1984 Act to allow such procedures to be carried out by widening the definition of anatomical examination so that it is not restricted to dissection but to any act that is done for teaching, training, studying or research purpose on a body. This would include implantation, removal of body parts, and the remodelling of existing tissue to construct a replacement for a part of the body that has been removed.

71. The second principal area of the policy intention is to address public concerns over the use of bodies and body parts in public exhibitions under the guise of education or art. An attempt was made to display bodies as part of the 2003 Edinburgh Festival Fringe, and considerable controversy was raised by the “Bodyworks” exhibition which displayed dissected freeze-dried corpses. However, the 1984 Act as presently framed did not allow any action to be taken to prevent such displays so long as the bodies had been acquired and dissected outside the UK.

72. The policy intention is therefore to take on sole power for Scottish Ministers to licence the public exhibitions of anatomical specimens, or public dissections, for the purpose of education, training and research into morphology. This will have the effect of preventing any unlicensed exhibition. A mechanism to allow a right of appeal against the refusal of a licence is being introduced for the first time. The lack of a mechanism for appeal does not appear to have caused any serious difficulty in the past 20 years, but nevertheless the need to provide such a
right was thought appropriate given the tightening of the licensing regime and in the light of current employment and human rights legislation.

73. The third principal policy intention is to put in place structures to enable the post of HM Inspector of Anatomy for Scotland to be continued following changes in the rest of the UK, whether by contract with the Human Tissues Authority, or any successor body, or any other qualified body or person, to carry out the functions required of HM Inspector.

74. In addition to these principal areas it is also intended to introduce provisions to regulate the importation of bodies or body parts, which at present are not subject to any control, and to prohibit the use of bodies for financial gain. These are in line with changes in the rest of the UK and will prevent potential abuses which the law as it stands might allow.

75. Finally, there is an intention to amend the law to allow Scottish Ministers to prepare a Code of Practice (and this will be done in consultation with key stakeholders) which will set out guidance on the conduct of anatomical examinations and the use of body parts following such examination where there is authority to retain the body parts.

Alternative Approaches

76. The consultation document explored the continuing need for an Anatomy Act and concluded that, although there were technological advances that contributed to surgical training (i.e. restructured animal tissue models, synthetic tissue models and virtual reality simulation developments) there would be a need for some time for strictly regulated use of human cadavers for skills training relevant to surgery and other recognised medical specialities. There was no dissent from this viewpoint.

77. The responses to the consultation supported updating and amending the Anatomy Act 1984 to deal with advances in surgical techniques and deficiencies in the Act over public display of bodies and body parts and future inspection arrangements.

78. The consultation outlined the proposed Inspectorate arrangements (setting up of the Human Tissue Authority) for the rest of the UK. In line with the responses to the consultation the option has been left open for Scotland to share inspection arrangements with England & Wales (as is the case at present), or for Scottish Ministers to appoint a dedicated (part-time) Inspector of Anatomy for Scotland, should a shared inspectorate prove to be impractical.

Consultation

79. The Executive carried out a consultation exercise on the proposed changes. The response was moderate in terms of numbers (43 responses) but broad in terms of types of stakeholders represented amongst respondents (including NHS Health Boards, University Medical Schools, General Medical Council, British Medical Association, HMIAS, Royal Colleges of Nursing, Paediatrics and Pathologists, Anatomical Society of GB and Ireland). There

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was general support for the proposed changes to the legislation. A report containing an independent analysis of the responses to the consultation was published on 28 February 200514.

**Effects On Equal Opportunities, Human Rights, Island Communities, Local Government, Sustainable Development Etc.**

*Equal Opportunities*

80. The provisions of the Bill are not discriminatory on the basis of gender, race, disability, marital status, religion or sexual orientation.

*Human Rights*

81. The Executive is satisfied that the provisions of the Bill are compatible with the European Convention on Human Rights. The concept of authorisation was developed from consideration of the Human Rights article which deals with the privacy of the family. There is a particular need in the hospital post-mortem examination context to be sensitive to the religious views of the family.

*Island Communities*

82. These provisions of the Bill apply equally to all communities in Scotland.

*Local Government*

83. The Executive is satisfied that the Bill will not have an impact on local government. The lead on implementing the legislation will fall to Health Boards with central support and guidance provided by the Executive.

*Sustainable Development*

84. *Meeting the Needs...* describes how building a national effort to improve health, reducing inequalities in health and making the NHS a ‘national health service’ and not a ‘national illness service’, is an integral part of sustainable development. The Executive has made clear that efforts to promote health, alongside programmes on social justice, crime and transport, are central to sustainable development.

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HUMAN TISSUE (SCOTLAND) BILL

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