wellcome trust

MRC Medical Research Council

HUMAN TISSUE (SCOTLAND) BILL

CALL FOR EVIDENCE BY THE HEALTH COMMITTEE
VIEWS OF THE WELLCOME TRUST AND THE MEDICAL RESEARCH COUNCIL

23 August 2005

Introduction

1 The Wellcome Trust is an independent research-funding charity, established under the will of Sir Henry Wellcome in 1936[1]. The Trust's mission is "to foster and promote research with the aim of improving human and animal health". The Trust supports a wide range of biomedical research throughout the UK and internationally, covering subjects as diverse as genetics, neuroscience, clinical research and scientific research in museums. The Trust also supports public engagement in relation to science, including through exhibitions that explore medical science in the context of society, culture and everyday life, and through the work of museums in the science field.

2 The UK Medical Research Council (MRC) is a national organisation funded by the UK government[2]. MRC aims to promote research into all areas of medical and related science in order to improve the health and quality of life of the UK public and contribute to the wealth of the nation. MRC also supports public engagement in research. MRC receives an annual Grant in aid from Parliament via the Office of Science and Technology and is independent in its choice of which research to support. MRC works in close partnership with Health Departments, other Research Councils, medical research charities, industry and others to identify and respond to current and future health needs. MRC's particular interest in the Human Tissue (Scotland) Bill ("the Bill") relates to the use of human tissue in research.

3 The Trust and the MRC took a strong interest in the development of the Human Tissue Act 2004 ("HTAct") and actively campaigned for its improvement. Like the HTAct, the Bill affects many of the areas that are of interest and concern to the MRC and the Trust.

4 In this submission, we provide a series of general comments about the Bill as introduced, a number of more specific points, and some recommendations. Our specific points relate to the requirements for existing holdings, public display and the extended definition of anatomical examination. We also include comments on the relationship and inconsistencies between Parts 1 and 2 of the Bill, hospital post mortems, the lack of definition of tissue, organs and body parts, the use of residual tissue for treating or diagnosing third parties or other purposes, and a number of comments relating to authorisation.

[1] http://www.wellcome.ac.uk/
[2] http://www.mrc.ac.uk/

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General comments

5 We support the introduction of legislation to clarify the law in this area. These are difficult and sensitive issues that deserve careful treatment in primary legislation to protect the public, maintain public confidence and facilitate teaching and research for public and patient benefit. We agree that the existing law in this area is inadequate for this purpose.

6 We support most of the principles of the Bill and overall, feel it is a proportionate piece of legislation, which sensibly balances the various interests at stake, although we have a number of specific concerns, which we have set out in this submission.

7 We welcome the decision to focus the legislation predominantly on human bodies and tissue from the deceased. Although this creates a difference with the approach in England, Wales and Northern Ireland, we believe the Scottish approach has advantages, notwithstanding the difference.

8 We are supportive of the proposal to issue guidance in relation to residual tissue from the living left over from diagnosis or treatment in line with the requirements of the HTAct rather than to regulate the use of this tissue through specific legislation and under a licensing system, the approach taken in the HTAct. We believe this is a sensible and proportionate approach to the issue.

9 We support the decision not to introduce a new licensing system regulating the storage of tissue from the deceased. We do not believe this is necessary in addition to the controls that already exist, in this Bill and elsewhere, in law, regulation, governance and professional practice.

10 We note that the Bill sets out Scottish Ministers' responsibilities to promote donation of body parts for transplantation. We believe it would be very helpful if this were extended to include a responsibility to promote their donation for medical research purposes for the public good.

11 We welcome the decision to underpin the Bill with a requirement for "authorisation". Although this creates a difference with the approach in the HTAct, we firmly believe authorisation to be the most appropriate term in the circumstances in which it is used in the Bill. Unlike "consent", for example, the term recognises that a range of people can grant authorisation, not just the individual from whom the tissue has come, and that they can do so either on that individual's behalf, or in their own right.

12 There are a number of specific points that concern us. These include concerns about aspects of the provisions relating to existing holdings, public display, and anatomical examination, as well as a number of drafting and other general points. Our concerns and recommendations for addressing them are set out in detail at paragraphs 14 to 27.

13 We have some concerns that differences between this Bill and the HTAct may cause practical difficulties and discourage research collaboration and activities involving Scotland and the rest of the UK. We have particular concerns in this regard about:

- research projects conducted across the UK or cross-border, and
- research in Scotland involving DNA analysis (which would be subject to both this Bill and the HTAct).

To mitigate these difficulties, we would urge that:

(a) Guidance is issued as a matter of urgency explaining the differences between the Scottish and the English/ Welsh/ Northern Irish legal positions,

(b) Specific guidance is provided on the net effect of this Bill and HTAct in relation to DNA analysis, and the collection and storage of tissue in Scotland for that purpose,

(c) The differences are kept to a minimum i.e. that harmonisation is generally sought, where appropriate, and

(d) Policies, procedures and practices in the NHS, including in the use of standard forms, are co-ordinated and harmonised across the UK as far as possible, in order to minimise bureaucracy, maximise efficiency and maximise public, patient and professional understanding.

Specific comments

14 Existing holdings

We welcome the exemptions in Sections 31, 42 and 43 for existing holdings. However, we note with some concern that the exemptions only extend to tissue removed for the purposes of post mortem examination, either by the procurator fiscal or otherwise. This is a much narrower exemption than that in the HTAct, which applies to all existing holdings of tissue. Taken with Section 14 (which prevents the removal or use of a part of the body of a deceased person for research, education, training, audit or transplantation without authorisation), this would appear, we assume inadvertently, to prevent the use of a range of teaching and research collections, including collections of historic human remains held in museums in Scotland, for which authorisation cannot be obtained (either because close relatives cannot be identified or are no longer alive). We would strongly urge that the exemptions are extended to all existing holdings of tissue from the deceased, bringing the Bill in line with the approach taken in the HTAct. If this is not done, we fear the Bill will prevent the use of substantial amounts of tissue already collected in Scotland for teaching and research.

15 Public Display

We are concerned to note that this Bill will introduce amendments to the Anatomy Act 1984 in relation to the public display of bodies, body parts and images of bodies and body parts disseminated via electronic communications networks that appear to significantly restrict these activities. It is not clear to us whether this is intended, but we believe this is the effect and do not consider this to be in the public interest. Our concerns are set out in more detail below.

- *Display of whole bodies*
  We are very concerned that the Bill appears to prevent the public display of human bodies used for anatomical examination. We recognise the need to regulate this activity to ensure that those personally affected and the public generally are protected from harm or offence. However, we see no reason to deny the public any prospect of access to displays featuring human bodies used for anatomical examination (which, with the broader definition applied by the Bill, captures most cases) and the educational potential these can offer. To prevent such access in any circumstance, when access to human bodies is permitted, on an exclusive basis, for medical students and professionals for educational purposes seems to us to be wholly inappropriate.

- *Display of body parts*
  We are also very concerned that the power to display *parts* of the human body will be very limited under the Bill.

  Firstly, it would appear that parts of a body removed for anatomical examination outside of Scotland may not be displayed publicly in Scotland at all. We see no reason for completely prohibiting the display of body parts imported into Scotland but permitting (with a licence) the display of body parts prepared in Scotland. This would seem to deny the public the opportunity to view foreign material that may be of significant didactic value, including collections of overseas remains held in Scottish museums or specimens prepared using techniques only possible outside of Scotland.

  Secondly, the grounds on which a licence to display a part of a body may be granted are surprisingly narrow. A licence to display can only be obtained where the display is for the purposes of “teaching, study or research” into “the gross structure of the human body”. This will limit the types of displays in a way we believe is unnecessarily restrictive. To illustrate, exhibitions of human material for the purposes of public health education (for example, about the effects of disease) or to increase public understanding of cultural, racial or spiritual diversity would appear to be outside the scope of activities for which a licence can be sought since they do not relate to “the gross structure of the human body”. We would strongly recommend that “informing” is added to “teaching, study and research”, and that the requirement that such activities be about the “gross structure of the human body” is removed.

- *Display of images of bodies and body parts via communications networks*
  We note that, unlike the HTAct, images of bodies and body parts displayed via an electronic communications network are regulated in a similar way to the bodily material itself. Although we recognise that such use of these images needs to be controlled, we are unconvinced that this needs to be controlled to the same extent as the bodily material. Our concerns in relation to display of bodily material apply equally to the display of electronic images via networks. The dissemination of such images by electronic means can be an important research and teaching tool. The regulation of such activity through a licensing system is excessive and disproportionate.

In conclusion, we strongly urge the Health Committee to remove the prohibition on the public display of whole bodies used for anatomical examination (as redefined under this Bill), and of bodies and parts of bodies imported from outside of Scotland, and to extend the scope of the purposes for which human tissue and bodies can be publicly displayed. We would also urge that the public display of existing holdings is exempt from the requirements of this section and that the extension of the controls to images displayed electronically is reconsidered. We believe the Bill is inappropriately restrictive in these regards and will hamper Scotland's ability to display material that is (we believe quite appropriately) available to the public in other countries. The removal of these restrictions will (subject to the controls of the licensing system) open up opportunities for increasing learning, and public understanding and awareness that would otherwise be lost.

16 Definition of anatomical examination under the Anatomy Act 1984

We welcome the broadening of the definition of anatomical examination under the Anatomy Act 1984 with the aim of extending the types of anatomical procedures that can be licensed by the Inspector of Anatomy for teaching and research purposes. We believe this is entirely appropriate for the reasons set out in paragraph 65 of the Policy Memorandum to the Bill. However, we are concerned that, inadvertently, the definition has now been rendered so broad as to capture materially different types of activities. The words "carrying out a procedure on or in relation to…" to be inserted as new sub-Section 1(1)(b) of the Anatomy Act 1984 would appear to extend the scope of "anatomical examination" into research and teaching activities conducted on historical human remains by museums and similar institutions. This would appear to have the effect of bringing such activities within the remit of the licensing regime under the Anatomy Act, a step we do not consider to be necessary or appropriate. Accordingly, we would urge the removal of the words "carrying out a procedure on or in relation to…" in this sub-Section.

17 Relationship and inconsistencies between Parts 1, 2 and 3 of the Bill

We have some concern that the relationship and differences between Parts 1, 2 and 3 of the Bill, insofar as they affect the removal and use of tissue for research and teaching, are unclear and will cause difficulties in practice. There seems to be some overlap between Parts 1, 2 and 3, each of which regulate the removal and use of tissue for research, but the requirements differ in some instances. For example:

- under Part 1, it is not possible for a relative to authorise the removal or use of tissue for research. However, under Part 2, a post mortem examination may (according to Section 19) be conducted for the purposes of removal of tissue for research with the authorisation of a relative. In this case, we would strongly support permitting a relative to authorise the removal and use of tissue for research, in line with the approach in the HTAct;

- it is unclear how section 23(6) interacts with Part 1, if at all. If it doesn't, it would appear to create an odd inconsistency between Parts 1 and 2;

- it is not clear whether tissue removed (with authorisation) for the purposes of research by a procurator fiscal during a post mortem is regulated by Part 3 (which appears only to relate to tissue removed for the purpose of the post mortem) or Part 1 (which relates to the removal of tissue for research outside of post mortem).

These inconsistencies, and the relationship between Parts 1, 2 and 3 generally, need further consideration, as the requirements are currently unclear and in some cases contradictory.

18 Hospital post mortems

We welcome the provisions in Part 2 of the Bill relating to hospital post mortems. In particular, we support the approach the Bill takes to authorisation of hospital post mortems. The Bill confirms that authorisation of a post mortem automatically includes authorisation to retain and use tissue removed during the examination for teaching and research (assuming our reading of Section 23(1)(b) is correct – we assume that the words "for the purposes of audit, education, training or research" rather than "for any of those purposes" should appear at the end of the sub-section). We believe this is a sensible and balanced approach, provided that it is reinforced by measures to ensure that those granting authorisation understand this is the effect. The use of suitable authorisation forms and information leaflets to supplement the approach in the legislation will be key. In that context, we would urge that draft authorisation forms are made public for consideration alongside this Bill, together with information about plans within the NHS in Scotland for introducing such materials and increasing public awareness generally.

We also support the slightly different approach taken in relation to organs. We recognise people commonly have a different emotional response to whole organs than they have to tissue and thus a separate request for authorisation of the retention and use of organs for teaching and research is appropriate. However, as we indicate below, the difference between an organ and tissue may not be easy to draw in practice, so suitable definitions and guidance will be necessary.

19 Definitions of tissue, organs and body parts

We note that the terms 'tissue', 'tissue samples', 'organs', and 'body parts' are used in the Bill but not defined. Although we recognise the difficulties of defining these concepts, we believe it is essential to do so, either on the face of the Bill or in codes of practice. For example, under Section 23(6) of the Bill, no material other than an organ, a tissue sample, blood, or other bodily material may be retained after a hospital post mortem. It is unclear whether this prevents the retention of material such as skin, hair or nail, for example. If this is the intention, this is of concern, as we see no reason for it. Generally, the distinctions between these terms have a material affect on the legal obligations under the Bill and therefore must be clear.

20 Use of residual tissue for treating or diagnosing third parties

We welcome the inclusion of the power under Section 34(b) to use tissue leftover from a procurator fiscal post mortem for the purposes of obtaining health information about any other person but we question why this is not also explicitly permitted in relation to hospital post mortems under Part 2, and more generally under Part 1.

21 Use of residual tissue for other purposes

We are unclear as to whether tissue lawfully removed from deceased persons can be used for any of the following purposes without authorisation. We would assume so, but would welcome clarification of this:

- public health surveillance or monitoring
- treating or diagnosing a third party (other than following a procurator fiscal post mortem, for which the position is made clear in Part 3 of the Bill)
- public display of tissue which is not an anatomical specimen under the Anatomy Act 1984.

22 Breadth and duration of authorisation

We indicate earlier in our submission that we are supportive of the use of the term authorisation in this Bill. In our view, an important feature of authorisation is that it can be given for general purposes (e.g. 'for research'), for an indefinite amount of time, provided the person giving the authorisation understands that is the effect. We believe this is both necessary and appropriate. It is impracticable to seek authorisation for each use of tissue in every case and risks overburdening the individuals concerned unnecessarily where they are quite willing to give a broad and enduring authorisation. For the avoidance of confusion, we would urge that this feature of authorisation is made clear in any guidance and in statements in Parliament.

23 Conditions on authorisation

We note that under Section 44, it is expressly provided that conditions can be imposed on authorisation. We are concerned that it is inappropriate to state this explicitly in the legislation in this manner and that this may have unforeseen consequences for other legislation. An equivalent provision is not included in the HTAct, yet, it would incorrect to conclude from that that conditions cannot be imposed on any consent given under the HTAct. Similar arguments can be made in respect of other legislation. We are also concerned that the Section indicates that once conditions have been specified, "the matter must be carried out in accordance with the conditions". We would strongly urge the addition of the word "only" after "must", otherwise, it would appear that the person seeking authorisation would be obliged to proceed with the act being authorised, when he or she may prefer not to proceed at all.

24 Formalities for obtaining authorisation

We are concerned that some of the formalities for obtaining authorisation are overly prescriptive, and also vary significantly across the Bill. For example, we question why authorisation by a relative under Parts 1 and 2 of the Bill needs to be in writing and in the latter case (but not the former), needs to be witnessed by two witnesses. We would urge the Committee to consider reducing the formality required on the face of the Bill, in line with the much simpler approach taken in the HTAct, and to address the use of such formalities through guidance on best practice. If the current approach in the Bill is retained, there is a significant risk that the wishes of patients and their families will not be respected where there is a failure in a signing formality, and that the benefits this could have conferred on others will be lost. We would also urge the Committee to ensure as far as possible that where formalities are required, they are as consistent as possible across the Bill to maximise efficiency and minimise confusion. Where they differ (for example, in relation to children and adults - oral authorisation is unacceptable for the former), the reasons for this should be clarified.

25 Hierarchy for relatives giving authorisation

We note that under Section 45(4)(b)(ii), where there is more than one relative who might give authorisation in any particular category (child, parent, sibling etc), a hierarchy based on age applies. We would urge the Committee to reconsider this hierarchy and take the approach in the HTAct by allowing any member of that category to give authorisation. We see no ethical basis for the rule, and considerable practical difficulty for the practitioner who is seeking authorisation in trying to ascertain the identities and ages of all those in the relevant category.

26 Written request to be treated as authorisation

We note in Section 8 that a request in writing from an adult that part of their body be used after their death for transplantation may be treated as authorisation under Part 1 of the Bill. We would strongly recommend, in order to ensure that the wishes of individuals are respected, this Section also extends to use for research and teaching.

27 Research where it is inappropriate to seek authorisation e.g. sudden infant death

Although we support the general principle that research using tissue from the deceased should only proceed with appropriate authorisation, we note this creates a particular difficulty for certain types of research where it is inappropriate to seek authorisation. A clear example of this arises in the case of research into sudden unexplained infant death, where it may be inappropriate to seek the authorisation of either parent if their involvement in the death is suspected. Further research in this area is needed to improve the diagnosis and treatment of this syndrome but will be difficult to undertake if provision is not made, in exceptional circumstances, for an alternative method of authorisation. We would ask the Committee to consider an alternative to deal with such circumstances, in order that important research in this area can proceed.