

Twenty Ninth Meeting of the Human Tissue Authority

Date 17 June 2008
Time 10.30am – 1pm
Venue The Law Society
113 Chancery Lane,
London
WC2A 1PL

Agenda

(I) = for information; (D) = for decision

1. Welcome and apologies
2. Declarations of interest
3. Minutes of 20 May 2008 HTA (22/08)
4. Matters arising
5. Chair's report (I)
6. Chief Executive's report (I) HTA (23/08)
7. Financial report (I) HTA (24/08)
8. Draft revised code of practice on Anatomical Examination (D) HTA (25/08)
9. Annual Review (I) HTA (26/08)
10. Report back from Audit Committee (I) Verbal
11. Annual Report and Accounts (D) HTA (27/08)
12. Codes revision: consultation arrangements (I) HTA (28/08)
13. Directed deceased donation: update Verbal
14. Any other business

Lunch

Minutes of the twenty eighth meeting of the Human Tissue Authority

Date 20 May 2008

Venue The Royal College of Anaesthetists
Churchill House
35 Red Lion Square
London WC1R 4SG

Present	
Members Ms Shirley Harrison (Chair) Professor Michael Banner Mrs Jodi Berg Dr Kate Robson-Brown Mr Brian Coulter Dr Ceri Davies Mrs Pamela Goldberg Professor James Ironside Professor El-Nasir Lalani Ms Ruth Musson Mr Keith Rigg Ms Catharine Seddon Ms Helen Shaw Professor Sir James Underwood	In attendance Mr Adrian McNeil (Chief Executive) Mr Leslie Boodram (Director of Resources) Dr Shaun Griffin (Director of Communications) Mr Peter Lemmey (Director of Policy) Dr Sandy Mather (Director of Regulation) Ms Priya Goyal (Authority Secretary) Observers Mr Peter Jones (DH) Mrs Kristi Adams Ms Rosanna Bate Ms Claire Bithell Mr Steve Blades

Item	Title	Action
Item 1	Welcome and apologies	
	<ol style="list-style-type: none"> 1. Shirley Harrison welcomed the four new Authority members who were attending their first meeting. 2. She also welcomed the following observers from the HTA executive: Rosanna Bate (Policy Officer), Claire Bithell (Media Manager) and Steve Blades (Project Manager). Kristi Adams (Head of Regulation) was attending to note members' comments on the draft code of practice on Research. 3. Apologies had been received from Dr Andrew Reid and Ms Michaela Willis. 	
Item 2	Declaration of interests	
	<ol style="list-style-type: none"> 4. Ruth Musson declared an interest in the ethical approval sections of the research code as member of a Research Ethics Committee. 5. Shirley Harrison said that members' updated annual declaration of interests would shortly be published on the website. 	
Item 3	Minutes from 22 April 2008 [paper: HTA (17/08)]	
	<ol style="list-style-type: none"> 6. Subject to the following changes the minutes were agreed as an accurate record: <ul style="list-style-type: none"> • Covering page: Mr Keith Rigg and Ms Helen Shaw to be added to the list of members present at the meeting. • Paragraph 12: amendment dealt with at item 4, paragraph 7 below. 	PG
Item 4	Matters arising	
	<ol style="list-style-type: none"> 7. Paragraph 12, Code of Practice on the Disposal of Human Tissue, Retention and disposal of tissue following coroner's post-mortem examination: Adrian McNeil said he had been asked by Andrew Reid to say on his behalf that he disagreed with retention of tissue for any period of time following the end of the coroner's authority. He thought it was inappropriate and potentially unlawful to keep tissue without consent. 8. Some members said that the minutes had incorrectly recorded as an agreement that tissue should be kept for up to three years pending the decision of the family. Their recollection was that this proposal had been made as an interim measure until agreement was reached. It was agreed to amend the first bullet of the minute. 9. Adrian McNeil said that a meeting had been arranged 	

Item	Title	Action
	<p>with André Rebello, the honorary secretary of the Coroner’s Society, along with representatives from the Royal College of Pathologists, the DH and the Ministry of Justice on 26 June to discuss a protocol between coroners and pathologists. However, it was agreed that before this meeting took place, the Authority needed to decide what position it wished to take on disposal. A small group of members would meet to do this.</p> <p>10. Paragraph 8: Leslie Boodram said that the Authority was still awaiting an answer from the DH about the business case for an increase in GIA. He explained that the DH had asked for an impact assessment that addressed what work could be dropped if the increase was not agreed. This would be submitted to the DH in the next few days. The assessment would point out that living with the deficit would result in the Authority not being able to meet its statutory remit.</p> <p>11. Shirley Harrison said that not to have the additional funding would present a substantial risk to the Authority and asked Peter Jones to relay to his finance colleagues in the DH the urgent need to make an early and favourable decision.</p>	LB/PJ
Item 5	Chair’s Report	
	<p>12. Shirley Harrison said that she had attended the Organ Donation Task Force meeting on 6 May where she had spoken about the systems for living and deceased donation.</p> <p>13. She reported that the Authority had held a workshop on directed deceased donation (DDD) on 19 May, which Authority members and experts in ethics and representatives of other organisations had attended. The workshop had been very helpful in bringing out the issues and complexities of DDD.</p> <p>14. The Authority members’ ad hoc group on DDD had discussed the outputs of the workshop and felt that, before any policy decisions could be made, a paper was needed that set out the locus of the HTA, UKT and the DH in taking this matter forward.</p>	PL
Item 6	Chief Executive’s Report	
	<p>15. Adrian McNeil introduced this item. He explained that this was the first report in the new format which reported progress against milestones.</p> <p>16. He apologised for the error under objective 4: he had</p>	

Item	Title	Action
	<p>attended the Istanbul Summit on transplantation, but not with the President of the Anatomical Society.</p> <p>17. Objective 21: Brian Coulter asked about the induction day on 12 June for new members. Leslie Boodram said that an agenda for the day would be sent shortly.</p> <p>18. Objective 5: Kate Robson-Brown asked about the meeting with York University. Shaun Griffin said that this meeting had been held with two academics to discuss proposals for measuring the effectiveness of the Authority's work.</p> <p>19. Objective 11: Ruth Musson asked about the classification of tissue blocks and slides. Sandy Mather explained that a paper had been sent to the Scientific Panel proposing how to deal with this issue and that a paper confirming their decision would be circulated shortly.</p> <p>20. Objectives 2, 3 and 14: Sandy Mather said that the capacity of the regulation team was very stretched because of the extra work generated by the licensing of procurement organisations under the Quality and Safety Regulations. Resources had been diverted from site visit inspections which would result in a reduction of the overall target for site visits inspections for the year.</p> <p>21. Pamela Goldberg was concerned that this put the Authority in a difficult situation and asked how and why there was a shortage of resources. Sandy Mather explained that the headcount limit had been set by the DH in late 2006. The complexity and volume of work and the addition of new work pointed to the need for additional resources if the Authority was to continue to meet its statutory remit. Peter Jones said that the headcount could be reviewed if the Authority was not able to carry out its statutory functions.</p> <p>Communications report</p> <p>22. Shaun Griffin said that there had been significant media activity surrounding directed deceased donation and that the Authority had responded to all enquiries that had been received from members of the public.</p>	LB
Item 7	Draft Code of Practice on Research [paper: HTA (19/08)]	
	<p>23. Peter Lemmey introduced the paper. He said that this was a new code and explained the stages it had been through in its preparation. He also drew members' attention to the new generic introduction. He added that a paper would be submitted to the Authority in June to set out the consultation arrangements for all the codes.</p>	PL

Item	Title	Action
	<p>24. He referred members to the specific issues set out in the covering paper and the following points were raised:</p> <p><i>Definitions</i></p> <ul style="list-style-type: none"> • The definition of ‘research’ should be reworded to read: ‘a study which addressed clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, functioning and/or disorders of the human body’. A scenario should be added to illustrate the definition. • A definition of ‘audit’ should be included and clarified by way of a common scenario. • The definition of ‘storage’ should be more precise. <p><i>Ethical approval</i></p> <ul style="list-style-type: none"> • Paragraphs should include reference to ethical approval where appropriate. <p><i>Relevant material from diagnosis and post mortem</i></p> <ul style="list-style-type: none"> • The second sentence should be reworded to read: ‘The primary purpose of the archive must be for diagnostic purposes and the relevant material must not be routinely distributed’. • A reference to the list of relevant material, when finalised, should be included. <p>25. Members were requested to send detailed textual comments via email to Kristi Adams.</p> <p>26. Subject to the agreement of any significant amendments via email, the Authority approved the draft of the code for consultation.</p>	
Item 8	BERR Statutory Code of Practice for Regulators [paper: HTA (20/08)]	
	<p>27. Sandy Mather introduced this paper and explained its implications for the Authority and how it linked to the planned Hampton Implementation Review.</p> <p>28. She explained that on initial review of the 37 requirements in the Code, the Authority appeared to be either fully or partially compliant with them all. The requirements of the Code would be carefully reviewed and an action plan developed for how the Authority could work towards compliance with all its requirements.</p> <p>29. Members noted the introduction of the BERR Statutory Code of Practice for Regulators and the actions the Executive proposed to take in light of it. They felt that the auditors of the Authority’s business and regulatory methods should avoid overlap and adopt a proportionate</p>	SM

Item	Title	Action
	<p>approach. They endorsed the recommendation to request the Better Regulation Executive to schedule the Hampton Implementation Review for the fourth quarter of the 2008/09 business year.</p>	
Item 9	Quarterly Regulatory Action Report [paper: HTA (21/08)]	
	<p>30. Sandy Mather introduced this paper.</p> <p>31. She explained how the Regulatory Action Panels operated and that they had been set up to ensure that robust and defensible licensing decisions were made.</p> <p>32. Members noted the regulatory action taken by the Regulation Directorate between November 2007 and March 2008.</p>	
Item 10	<p>Report back from Audit Committee</p> <p>33. Michael Banner reported that the Audit Committee would meet immediately after the Authority meeting.</p> <p>34. He said that eight areas of internal audit had been undertaken. Seven had achieved a “substantial” assurance and one an “adequate” assurance. The end-year audit being conducted by the National Audit Office would be completed by the end of May.</p> <p>35. He added that the annual report of the Audit Committee would be presented to the Authority in July.</p>	MB
Item 11	Any other business	
	36. None was raised.	

The meeting closed at 1.20pm

Authority Paper

Date	17 June 2008	Paper reference	HTA (25/08)
Agenda item	8	Author	Peter Lemmey

Draft revised code of practice on Anatomical Examination

Introduction

1. This paper invites the Authority to approve the draft of the revised code of practice on anatomical examination, so that it can be consulted on formally.

Background

2. The first revision of the Authority's codes of practice is now under way. This is an important strand of the current business plan, and Members have already been involved in the process through the Members' Policy Group (MPG) meetings, by commenting on drafts of individual codes, and in discussions at previous Authority meetings. Public consultation on the agreed set of eight draft codes will take place over 15 weeks from the beginning of August: there is a separate note about the consultation arrangements on the agenda. The Authority has so far seen and commented on drafts of seven of the revised codes.

Discussion

3. The eighth in the set is the code of practice on anatomical examination. The codes revision programme board agreed that the revised version of this code should follow the pattern and approach adopted in the original version of the anatomical examination code, albeit subject to the guidelines agreed for the revision exercise. The draft of this revised version of the code has been considered in detail by the Members' Policy Group and the attached draft reflects the Group's comments.

4. Following approval of the text by the Authority the draft code will be consulted on formally, together with the HTA's other draft revised codes of practice.

Conclusion

The Authority is invited to agree the attached draft of the revised code of practice on anatomical examination.



The Human Tissue Authority

Code of Practice

Anatomical Examination

Code 4

Contents

	Paragraphs
Introduction	1–24
Scope of this code	25–26
Status of this code	27
Obtaining appropriate consent	28–37
Licensing	38
Existing anatomical specimens	39–40
Providing information to potential donors	41–42
The use of images	43–45
Documentation and record keeping	46–48
HTA standards:	49–68
• Governance and quality systems	52–62
• Premises, facilities and equipment	63–67
• Disposal	68
Care of cadaveric material	69–70
Transfer or loan of cadaveric material	71–76
Import and export of bodies or body parts	77–79
Charging	80
References	
Appendices	
Glossary	
Introduction	
About the Human Tissue Authority	

Role of the Human Tissue Authority

1. The Human Tissue Act 2004 (HT Act) [link to: http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_6#sch1] established the Human Tissue Authority (HTA) to regulate activities concerning the removal, storage, use and disposal of human tissue (referred to as relevant material [glossary link] in the HT Act). Activities covered by the HT Act are referred to as scheduled purposes [glossary link or link to relevant section in the HT Act].
2. The HTA has several statutory functions. One is to inform the public, professionals and the Secretary of State for Health about issues within our remit. We meet this requirement for professionals by providing guidance, including codes of practice, to support good practice.

Regulation through licensing

3. Another statutory function is to regulate, through licensing, a number of sectors and to carry out inspections to ensure licence conditions are being met. The HTA publishes standards that licensed establishments must meet: on consent; governance and quality systems; premises; facilities and equipment; and disposal. The sectors licensed under the Human Tissue Act are:
 - Anatomy
 - Post mortem services
 - Human application (transplantation of tissues and cells; see below)
 - Research
 - Public display
4. The HTA is the Competent Authority in the UK responsible for ensuring the safety of human tissue and cells that are used for transplantation in compliance with the European Union Tissue and Cells Directive (EUTCD).

Regulation of living and deceased donation

5. A third statutory function is the regulation, through a system of approvals, of the donation from living people of solid organs, bone marrow and peripheral blood stem cells for transplantation into others. The HTA, Independent Assessors and Accredited Assessors who work on behalf of the HTA, assess whether consent requirements for donation have been met, and act as representatives for the donors. The HTA also regulates living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.

6. The HTA also oversees the consent requirements of the HT Act for deceased organ donation.

Legislation and statutory framework

Human Tissue Act 2004

[http://www.opsi.gov.uk/acts/acts2004/ukpga_20040030_en_1]

7. Consent is the fundamental principle of the HT Act. The legislation covers England, Wales and Northern Ireland, and sets out the legal framework for:
 - the storage and use of human tissue from living people.
 - the removal, storage, use and disposal of tissue from the deceased.
8. Regulations issued under the HT Act, which provide more detail, include:

The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplant) Regulations 2006

[<http://www.opsi.gov.uk/si/si2006/draft/20064576.htm>]

The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. [<http://www.opsi.gov.uk/si/si2006/20061260.htm>]

9. Consent for diagnosis or treatment is not in the scope of the HT Act.

Human Tissue (Scotland) Act 2006

[http://www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_1]

10. The HT Act covers England, Wales and Northern Ireland, and there is separate legislation for Scotland, the Human Tissue (Scotland) Act 2006 [http://www.opsi.gov.uk/legislation/scotland/acts2006/asp_20060004_en_1].
11. Authorisation, rather than consent, is the fundamental principle of the HT (Scotland) Act; both are expressions of the same principle.
12. Guidance on the Human Tissue (Scotland) Act 2006 is available in the Scottish Health Department Letter: Human Tissue (Scotland) Act 2006: A Guide to its Implications for NHS Scotland [[http://www.hta.gov.uk/db/documents/Information_about_HT_\(Scotland\)_Act.pdf](http://www.hta.gov.uk/db/documents/Information_about_HT_(Scotland)_Act.pdf)], and practitioners working in Scotland should ensure they are familiar with this guidance.]

Human Tissue (Quality and Safety for Human Application) Regulations 2007

13. The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Q&S Regulations) govern the quality and safety of tissue and cells (not including solid organs) used for transplantation. The Q&S Regulations brought the EUTCD into force in the UK, including Scotland. [links to Regs].
14. There is no code of practice for establishments using tissue and cells for transplantation. However, the HTA issues Directions for these establishments which set out expected standards. Directions 001/2006 summarise the requirements of the parent and first technical Directive of the EUTCD (Directives 2004/23/EC and Directive 2006/17/EC). Directions 002/2007 set out the requirements of the Regulations 2007 and the second technical Directive (Directives 2004/86/EC), and supplement and amend Directions 001/2006. [links to Directions page of website].

Codes of practice

About the codes

15. The codes give practical guidance to professionals carrying out activities which lie within the HTA's remit. They may also be of interest to members of the public. The first editions of the codes have been revised to reflect our experience of regulation. We have made the codes more relevant to the sectors we regulate by including case studies and examples; and have restructured them in a way that makes them more user-friendly.
16. They are supplemented by other more detailed guidance, for example on licensing standards, which can be found on the HTA's website.
17. Failure to follow a code of practice is not in itself a criminal offence under the HT Act, but the HTA may take a breach into account when carrying out its regulatory responsibilities. For licensed establishments, adherence to the HTA's codes of practice is assessed as part of the licensing and inspection activities.
18. The HTA has now published nine codes of practice, which are listed below:[Link to: http://www.hta.gov.uk/guidance/codes_of_practice.cfm]
 1. Consent
 2. Donation of organs for transplantation
 3. Post-mortem examination

4. Anatomical examination
 5. Disposal of human tissue
 6. Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation
 7. Public display
 8. Import and export of human bodies, body parts and tissue
 9. Research
19. All nine codes of practice have been brought into force by HTA Directions and replace the codes previously published by the HTA.
[\[http://www.hta.gov.uk/guidance/licensing_guidance/expected_standards_directions.cfm\]](http://www.hta.gov.uk/guidance/licensing_guidance/expected_standards_directions.cfm)

Using the codes

20. The codes complement each other and should be read alongside other relevant guidance, either referenced in the text or provided on the HTA website (www.hta.gov.uk).
21. The codes of practice are available in pdf form for printing, and in HTML format, which allows the reader to navigate through the codes more easily when viewed online.
22. The HTA will update these codes from time to time, and will issue Directions to bring them into force following the appropriate approval process.

Other advice and guidance

23. The HTA website provides extensive guidance to help ensure that the sectors we regulate comply with the law and embrace best practice. This includes guidance for licensed sectors and the transplant community, patient and public leaflets, and a bi-monthly e-newsletter.
24. A number of other organisations have also produced guidance on issues in the HTA's remit. Where this has been produced in collaboration with the HTA, it will appear on our website. But as a general rule, we would always advise that the HTA's codes of practice and other guidance are used as the definitive source of information for issues within our remit. If you are in any doubt, please

contact the HTA, or seek your own legal advice. Regulated sectors should also keep up to date with other relevant legislation.

Scope of this Code

25. The Human Tissue Act permits, with consent, the donation of whole bodies for anatomical examination. It also allows for the storage and anatomical examination of a body, provided that it is carried out by or under the direction of a Designated Individual, with consent, and providing that the death has been properly certified and registered.
26. This Code provides guidance for people working in the anatomy sector and sets out the requirements that establishments must meet in order to hold a licence to carry out anatomical examinations or to store anatomical specimens.

Status of this code

27. This code replaces the previous HTA code of practice and has received Parliamentary approval.

Obtaining appropriate consent

28. Under the Human Tissue Act, appropriate consent for anatomical examination can only be given by individuals who choose to donate their body; consent cannot be given by someone else.
29. For the consent for body donation to be valid under the Act, it must be in writing and:
 - signed by the donor in the presence of at least one witness who attests their signature; or
 - signed by a representative at the direction of the donor, in their presence and in the presence of at least one witness who attests their signature. The HTA accepts that it may not always be possible to obtain written consent from the individual who has chosen to donate their body or part of their body for anatomical examination, as when a mentally-competent person is physically unable to write. The HTA has therefore produced a [model form for a representative to sign on behalf of a donor](http://www.hta.gov.uk/search.cfm?FaArea1=CustomWidgets.content_view_1&cit_id=290&useCache=false) (available at http://www.hta.gov.uk/search.cfm?FaArea1=CustomWidgets.content_view_1&cit_id=290&useCache=false). In these circumstances, the HTA advises that:

- the potential donor has sufficient mental capacity to indicate verbally or physically that they wish to donate their body for anatomical examination. The professional assessment of mental capacity is beyond the scope of this Code;
- the representative should sign their own name, state that they have signed at the direction of the donor and explain the circumstances of this direction;
- the form must then be signed by a third party and may then be submitted to the receiving institution.

This procedure must occur prior to the donor's death. The consent form cannot be signed by the third party after death has occurred.

Example: A widower is suffering from a medical condition that has left him unable to communicate and unable to write. Many years ago, when he was well, he expressed an interest in donating his body for medical teaching after his death but did not take the matter further. Now the man is dying, his daughter wants her father's wishes to be complied with. Given the lack of documented consent and the inability to assess mental capacity, there is no way to confirm that the man wishes to donate his body for anatomical examination. Therefore, the offer of donation must be declined by the local medical school.

30. Documented and valid consent for anatomical examination given before 1 September 2006 is treated as appropriate consent under the Human Tissue Act.
31. Under the Human Tissue Act, appropriate consent is not needed for removal, storage and use of material from a deceased body for anatomical examination if the body has been imported, and neither is it needed if more than one hundred years have elapsed since the date of the person's death.
32. Anyone wishing to donate their body, or part of their body, for anatomical examination should preferably use an appropriate consent form, which must be kept as part of the donation records. The HTA has produced a model body donation consent form, which can be used or modified by establishments (available at http://www.hta.gov.uk/search.cfm?FaArea1=CustomWidgets.content_view_1&cit_id=163&useCache=false).

33. Individuals may indicate their choice to donate their bodies for anatomical examination in their will. In this case, an individual should be encouraged to fill in a consent form from their nearest medical school and to insert a copy in their will. The body donor should be made aware that, although a consent form does not have to be used in their will, the wording of their consent should resemble the wording on the consent form provided by the establishment to which they wish to donate their body.
34. Under the Human Tissue Act, the provisions for lawful *storage* of a body for the purpose of anatomical examination are different from the provisions for lawful *use* of a body for anatomical examination.
35. Storing a body for anatomical examination is lawful provided that:
- there is appropriate consent; and
 - there is a signed death certificate under the Births and Deaths Registration Act 1953 or in the case of Northern Ireland the Births and Deaths Registration (NI) Order 1976.
- This allows establishments to proceed to storage and timely preservation of a body donated for anatomical examination when registration of death has been delayed.
36. Using a body for anatomical examination is lawful provided that:
- there is appropriate consent; and
 - the person's death has been registered.
37. In the rare circumstance where a body has been donated for anatomical examination by a person whose death becomes the subject of a coroner's inquest but whose body is not needed for post mortem examination, the body may be preserved and stored for the purpose of anatomical examination. The body may not however be used for anatomical examination until the inquest has been completed and the death has been registered.

Licensing

38. Detailed guidance about the licensing framework is outlined in the HTA publication, [Guide to licensing for Designated Individuals and Licence Holders](#) (available at

http://www.hta.gov.uk/licensing/designated_individuals_and_licence_holders/dls_under_the_hta_act.cfm).

Existing anatomical specimens

39. Under the Anatomy Act 1984, anatomical specimens could only be used for anatomical examination during a period of three years from the date of the person's death. The Human Tissue Act provides for situations where material donated under the Anatomy Act 1984 was being held by anatomy establishments at the time the consent provisions of the Human Tissue Act came into force on 1 September 2006.
40. In relation to donations made under the Anatomy Act 1984 by people who died between 1 September 2003 and 31 August 2006, the Human Tissue Act states that:
- if anatomical examination had not been completed by 1 September 2006, the authority given under the Anatomy Act 1984 for anatomical examination can be treated as appropriate consent for storage and use for anatomical examination under the Human Tissue Act for three years from the date of a person's death or until the anatomical examination is completed, whatever is the shorter period; and
 - if anatomical examination is completed after 1 September 2006 but within three years of the person's death, authority given under the Anatomy Act 1984 to retain body parts can be treated as appropriate consent under the Human Tissue Act for their storage or use for research or education or training.

Providing information to potential donors

41. It is important that a person wishing to donate their body for anatomical examination is given all the information necessary to make an informed decision. This information should be made available in a variety of formats (electronic, written or face-to-face) so that donors can choose which is most appropriate for them. Information is also provided for potential donors on the How to donate a body webpage (available at http://www.hta.gov.uk/about_hta/donating_a_body_to_medical_science/how_to_donate_a_body.cfm) on the HTA website (available at <http://www.hta.gov.uk>).
42. The HTA has produced a model bequethal booklet and a model body donation consent form to aid anatomy establishments (both available at http://www.hta.gov.uk/about_hta/donating_a_body_to_medical_science/anatomy_schools.cfm).

The use of images

43. The making and displaying of images (including photographs, films and electronic images) is outside the scope of the Human Tissue Act. However, the HTA requires Designated Individuals to put systems in place to ensure suitable practices are carried out.
44. The HTA endorses the guidance about images provided by the General Medical Council (GMC) publication Making and Using Visual and Audio Recordings of Patients (available at http://www.gmc-uk.org/guidance/current/library/making_audiovisual.asp).
45. Ensuring suitable practices where licensable activities are concerned includes the Designated Individual ensuring that the dignity of deceased people is maintained at all times. Designated Individuals therefore need to put in place systems to prevent the inappropriate use of images.

Example: The Designated Individual of a university anatomy establishment fully understands her responsibilities under the HT Act. The establishment runs a very busy teaching facility, providing teaching to hundreds of healthcare students each year, some of whom attend from other universities. The Designated Individual is concerned that there is a small risk that the dignity of deceased people may not always be upheld. She acknowledges that physical supervision of all students at all times would be impossible but wants to put safeguards in place to avoid the risk of occurrence of such an event. After thorough discussions with the establishment's staff, the Designated Individual puts a number of new safeguards in place, including:

- *a review of the security of the premises*
- *a registration system, utilising a signing-in book so that the Designated Individual and other persons working under an HTA licence are aware of who is in the establishment at any given time. The reason for the visit should be recorded in the signing-in book, along with the name of the person under whose supervision the visitor will be.*
- *revising the local code of conduct to reflect the requirements of the HT Act and the HTA Code of practice on anatomical examination*
- *a declaration to be signed by all relevant visitors to confirm that they have read and understood the local code of conduct*
- *prominent signs relating to important aspects of the local code of conduct*

Documentation and record keeping

46. All places where anatomical examination is carried out should keep records in a permanent form for each body or body part in their possession (or in the possession of any other person authorised by the Designated Individual to

hold the anatomical specimen). These records must be held on the premises where the donated body was first received, and on any other premises to which the body or body parts may have been moved.

47. Records relating to body parts retained after anatomical examinations have been concluded must be held on the premises in which the examination of the original anatomical specimen took place, and on any other premises to which the parts may have been moved.
48. All records must be available for inspection and review at all times.

HTA standards

49. The HTA has developed a number of standards that establishments must comply with. These standards were developed in consultation with representatives of the anatomy sector. They reinforce the intention of the HT Act that consent is paramount for activities involving the use of human tissue and that dead bodies and tissue taken from them should be treated with respect and that the dignity of the person maintained at all times.
50. The HTA standards are grouped under the four headings: Consent (C); Governance and Quality Systems (GQS); Premises, Facilities and Equipment (PFE) and Disposal (D).
51. The following sections give guidance on the GQS, PFE and D standards. Guidance on consent is given earlier in this Code.

Governance and quality systems

52. The GQS standards focus on internal systems and processes that are in place to support staff in the delivery of high quality services.
53. As part of the overall governance process, the HTA requires that all aspects of an establishment's work are supported by ratified, documented policies and procedures. Documents must be ratified by a process involving more than one person and be subject to scheduled review.
54. An standard operating procedure (SOP) must be a clear and accurate representation of an existing procedure or process, preferably set out in the format of a stepwise guide. SOPs should be understandable in order that new staff are able to follow a standardised procedure

from beginning to end. They must be detailed enough to ensure uniformity between staff in the performance of a specific function and must be followed to the letter by all staff who been appropriately trained.

55. Meetings relating to licensable activities must be supported by an agenda and minutes and establishments must have a system for dealing with complaints from the public and other users.
56. The HTA requires establishments to have a documented quality management system in place, which need not to be electronic. It must, however, include a document control system, covering all documented policies and procedures.
57. The HTA requires Designated Individuals to ensure that all staff working under the authority of an HTA licence are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills. Staff training records must show qualifications, courses attended, evidence of attendance at induction and orientation training, evidence of recurrent appraisal and a personal development plan.
58. The HTA requires establishments to have a systematic and planned approach to the management of records, including documented procedures for the creation, amendment, retention and destruction of records. Record content must be audited regularly to ensure completeness, accuracy and legibility. Computerised records must be backed up and a system for data recovery must be in place. Data protection and confidentiality should be key components of the records system.
59. The HTA requires establishments to use a coding and records system that facilitates the traceability of bodies and separated parts, ensuring a robust audit trail.
60. The HTA requires that the establishment has a system in place to ensure that all adverse events are investigated properly and corrective and preventative actions are taken when necessary, to ensure that improvements in practice are made.
61. The HTA encourages establishments to advise it of serious incidents which adversely affect compliance with the HT Act and this code of practice in the following areas:
 - consent
 - the carrying out of the wishes of the deceased
 - the dignity of the deceased
 - the security, traceability, completeness and legibility of stored records
 - the security of licensed premises

62. The HTA requires that documented risk assessments of the establishment's practices and processes are completed regularly and are subject to scheduled review. Staff members must be able to access the risk assessments relevant to their work and be made aware of local hazards.

Premises, facilities and equipment

63. The HTA requires that premises are secure and appropriate for the purpose for which they are used. This means that a risk assessment must have been undertaken and that there are policies in place to review and maintain the safety of staff, authorised visitors and students. Policies to ensure that the premises are maintained to a standard that ensures the dignity of deceased persons must be in place as must policies to ensure that confidentiality is maintained.
64. Designated Individuals must ensure that suitable environmental controls are in place to avoid potential contamination. Documented cleaning and decontamination procedures must be in place and staff must be provided with appropriate personal protective equipment. Air quality and safe environmental conditions must be suitably maintained and appropriately monitored.
65. The HTA requires that establishments have appropriate facilities for the storage of cadaveric material, consumables and records; including a requirement that precautions are taken to minimise damage or theft.
66. The Designated Individual is responsible for the body and body parts of the deceased from the time of donation until the burial, cremation, disposal or return to the family. The HTA requires the Designated Individual to put in place documented policies and procedures for the transport of cadaveric material, including a risk assessment. Full traceability must be ensured during transportation; records of transportation and delivery must be kept. Records must also be kept of any transfer agreements with recipients of relevant material and of any written agreements with couriers or transport providers.
67. Equipment must be appropriate for use and documented contingency arrangements should be in place in case of equipment failure. Calibration, validation and maintenance records must be kept, along with any written

agreements with maintenance companies. Equipment users must have access to reliable instructions and receive training in safe use and maintenance where appropriate. Additionally, staff must be made aware of how to report equipment problems.

Disposal

68. The Designated Individual that accepts the body is responsible for its storage, examination and preservation until cremation or burial occurs or the body is returned to the family.

Care of cadaveric material

69. During anatomical examination and storage, all parts of the body must be treated with due respect and consideration.
70. It is good practice to retain tissue removed from the cadaver during dissection for disposal along with the body. Retained body parts and any tissue removed from them can be disposed of as clinical waste. These practices should be explained to the donor where possible at the start of the donation process.

Transfer or loan of cadaveric material

71. Bodies or body parts must be kept on licensed premises unless the Designated Individual has given written permission to a suitable nominated person to move them to appropriate unlicensed premises and to store and use them for authorised purposes.
72. Bodies or body parts can only be transferred or loaned for purposes for which consent was originally given.
73. Anatomical specimens or former anatomical specimens may be loaned by a Designated Individual, providing that the he or she puts the permission for each loan in writing. The loan should be for a defined time period and the written agreement should be signed by both parties.
74. Records should be kept of any loans, including relevant details of:
 - the specimen(s) covered by the agreement
 - the person authorised to hold the specimen(s)
 - the address where the specimen(s) will be held
 - the purpose for which the specimen(s) is/are being moved

- the purpose for which the authorised person may have possession of the specimen(s)
 - the period for which the loan is so authorised
75. The HTA has produced a model authorisation form for loan of anatomical specimens (available at http://www.hta.gov.uk/search.cfm?FaArea1=CustomWidgets.content_view_1&cit_id=290&useCache=false).
76. The Designated Individual remains responsible for the material for the duration of the loan. The HTA advises that the lender agrees to comply with the HT Act and Code of Practice on anatomical examination and that storage is appropriate.

Import and export of bodies or body parts

77. Body parts are imported into England, Wales and Northern Ireland for use primarily in education or training relating to human health. The import and export of relevant material is not licensable under the Human Tissue Act. However, the storage and use of relevant material for education or training relating to human health or for anatomical examination is licensable.
78. Imported material should be obtained, used, handled, stored, transported and disposed in accordance with the consent given by the person from whom it came. Importers should satisfy themselves and be able to demonstrate to the HTA that, in the countries from which they seek to import tissue, the gaining of consent for the purpose to which the tissue is subsequently put is part of the process by which the material is obtained.
79. The import and export of relevant material is discussed in detail in the HTA's Code of Practice 8 (available at http://www.hta.gov.uk/guidance/codes_of_practice.cfm).

Charging

80. Charges may be applied to cover the costs of transporting and embalming bodies and of preparing retained parts for use at other establishments. These charges should fairly reflect the costs involved.

References

Guide to Licensing for DI's and LHs-

http://www.hta.gov.uk/licensing/designated_individuals_and_licence_holders/dls_under_the_ht_act.cfm

Guidance on applying for a licence

http://www.hta.gov.uk/licensing/guide_to_licensing_and_application.cfm

General Medical Council publication, 'Making and Using Visual and Audio Recordings of Patients'

http://www.gmc-uk.org/guidance/current/library/making_audiovisual.asp

General Medical Council <http://www.gmc-uk.org>

Human Tissue Authority <http://www.hta.gov.uk>

Model consent forms http://www.hta.gov.uk/guidance/model_consent_forms.cfm

Mental Capacity Act (MC Act) 2005 http://www.opsi.gov.uk/ACTS/acts2005/ukpga_20050009_en_1

Code of Practice to the Mental Capacity Act 2005 <http://www.publicguardian.gov.uk/mca/code-of-practice.htm>

Glossary (DN: final version to be approved)

Authority Paper

Date	17 June 2008	Paper reference	HTA (26/08)
Agenda item	9	Author	Shaun Griffin

Annual Review 2007/08

Introduction

1. This paper presents the text for the HTA Annual Review 2007/08. This year the Annual Review is being published separately from the Annual Report and Accounts – the subject of a separate paper (HTA 27/08).

Background

2. The HTA has published two documents in one for the last two years:
 - **The Annual Review**
The Annual Review is an important tool in communicating the HTA's impact and achievements to our key opinion leaders and other stakeholders. The Annual Review does not need to be approved by National Audit Office (NAO) or laid before Parliament.
 - **The Annual Report and Accounts**
The Annual Report and Accounts consists of the information that we have a statutory obligation to produce and which must be signed off by the NAO and laid before Parliament. The content of this is prescribed by the Companies Act, the Government Financial Reporting Manual and Cabinet Office requirements.

3. As part of the 'faster closure programme' HM Treasury has set even more challenging dates for the completion, sign-off and production of this year's Annual Report and Accounts. This has been adopted by the Department of Health, with an additional objective of "expecting certification by the Comptroller and Auditor General by 23 June 2008".
4. It is expected that NAO will not sign off the HTA's Annual Report and Accounts until 23 June (although this date cannot be guaranteed). This fact, combined with the requirement to lay the Annual Report and Accounts as early as possible, means that this year's timetable does not allow time for the design and printing process.
5. For this reason, the Annual Review will be published as a separate document which is designed and includes photography. A limited number of printed copies of the Annual Review will be produced so that it can be distributed to key stakeholders and at our events. This year's Annual Report and Accounts will be laid before Parliament as a White Paper, so it will not be designed and only a few copies will be printed in-house.

Format and theme of the Annual Review

6. The theme of the 2007/08 Annual Review is confidence in regulation, hence the title '*Building confidence*'. The titles of each section demonstrate how we are delivering our strategic aim to "create a regulatory system for the removal, use and disposal of human tissue and organs that is clear, consistent and proportionate and in which professionals, patients, families and members of the public have confidence".
7. The Review includes an introduction by the Chair and Chief Executive and case study interviews linked to each of the sectors that we regulate. The Review follows a similar format to part 1 of last year's Annual Report but with more of a public and patient focus. The Review therefore includes interviews with both members of the public and professionals from the regulated sectors who interact with them. The published version of the Annual Review will include photographs of the Chair and Chief Executive and of the case studies.

Timetable

8. Following the Authority meeting there will be a four-week design and printing process. The Annual Review will then be published on our website and distributed to key stakeholders at the end of July. The Annual Review will also be distributed at our annual report-back meeting on 18 September.

Conclusion

9. The Authority is invited to comment on the document.

Human Tissue Authority

Annual Review 2007/08

Building confidence

Inside front cover text

This Annual Review covers the period 1 April 2007 to 31 March 2008.

The HTA's full Annual Report and Accounts are available at:

www.hta.gov.uk/about_hta/publications.cfm

Contents

- Chair and Chief Executive's introduction
- The HTA's remit and responsibilities
- Raising standards to provide the best basis for research
- Enabling more people to benefit from a living-donor transplant
- Ensuring that the wishes of individuals are respected
- Giving confidence to professionals and the public
- Playing a leading role in human tissue regulation in Europe
- Improving training for the health professionals of the future
- The year ahead

Chair and Chief Executive's introduction

We are very pleased to introduce our third Annual Review, covering the HTA's activity in 2007/8. This was a busy year in which we approved the thousandth living donor transplant and regulated nearly 800 establishments. We also commissioned research to discover what our stakeholders think about us and were pleased to find that professionals, patients, families and members of the general public have confidence in the regulation of human tissue. The continuing challenge for us will be to maintain and build on this confidence.

The pace, volume and complexity of the work has increased, largely because we are required to prepare for further regulation under the European Tissue and Cells Directive. Nonetheless, we are pleased to record that we have fully delivered on our widening remit. For such a small organisation this was an extraordinary feat which would have been impossible without the commitment, initiative and energy of staff and Authority members, who have continued to pull together to meet our goals for the year. We are very grateful for all they have done.

The HTA's stakeholders range from organisations that carry out research on human tissue and museums that display human bodies or body parts, to individuals who donate whole organs and bone marrow. This Annual Review describes the experiences of some of the people drawn from the sectors we regulate. We hope that this approach will give you a flavour not only of the diverse range of work that we are responsible for, but of the positive effect our regulatory activity has had.

In the autumn of last year, Ministers decided not to proceed with the creation of the Regulatory Authority for Tissue and Embryos (RATE). We are now looking to a future in which we continue to operate as a stand-alone arms' length body. We are determined that the principles and practices that have been a hallmark of the HTA should continue. This means that we will continue to deliver our statutory remit in a proportionate manner; provide comprehensive advice and guidance to the sectors we regulate; communicate with and engage our stakeholders; and deliver value for money.

By sticking to these principles and practices, we aim to continue to build on and retain the confidence of professionals and the public.

Shirley Harrison, Chair

Adrian McNeil, Chief Executive

The HTA's remit and responsibilities

The HTA's remit is to regulate the removal, storage, use and disposal of human bodies, organs and tissue from the living and deceased. We have several key statutory functions. One is to inform the public and the Secretary of State for Health about issues within our remit. We meet this obligation by issuing codes of practice including:

- Consent
- Donation of solid organs and tissue and cells for transplantation
- Post mortem examination
- Anatomical examination
- Removal, storage and disposal of human organs and tissue
- Donation of allogeneic bone marrow, peripheral blood stem cells and donor lymphocytes for transplantation
- Public display
- Import and export of human bodies, body parts and tissue
- Storage of tissue for research

Another statutory function is to regulate through licensing the following sectors:

- anatomy
- post mortem services
- tissue for human application (patient treatment)
- research
- public display

And a third is to regulate, through a system of approvals, all live organ donations within the UK and the donation of bone marrow for transplantation.

Finally, the HTA is one of two Competent Authorities under the EU Tissue and Cells Directive for regulating establishments importing, procuring, testing, storing, and processing and distributing tissue for human application.

The HTA has 42 staff and a board of Authority members. The professional members come from the medical and scientific backgrounds relevant to the HTA's remit; and the lay members bring a wide range of business, commercial and public sector experience.

The HTA's strategic aim is to create a regulatory system for the removal, storage, use and disposal of human tissue and organs that is clear, consistent and proportionate and in which professionals, patients, families and members of the public have confidence.

Raising standards to provide the best basis for research

Professor Richard Reynolds runs the Multiple Sclerosis (MS) Tissue Bank at Imperial College London. This organisation is licensed by the HTA to store human tissue for research. Medical research makes a vital contribution to improving healthcare, which is why Dave King agreed to donate his wife's brain when she died of multiple sclerosis (MS).

Professor Richard Reynolds, MS Tissue Bank

"I am Head of the Department of Cell and Molecular Neuroscience at Imperial College and one of the major aspects of my job is to run the UK MS Tissue Bank.

"It is rewarding for people to know they can make a lasting gift that may help future generations of MS sufferers. It is important that those who donate, and their families, know that tissue will be treated with respect and used only for good quality research.

"The study of human tissue affected by disease is absolutely vital in order to understand what is damaging the tissues. One of the biggest problems in our sector over the last 50 years has been variability of standards that can affect the outcomes of research. With the HTA, we now have an organisation that can make sure the appropriate standards are consistently applied across the board."

Dave King, donated his wife's tissue for research

"My wife, Doreen, had MS and we made the decision to donate her brain to the MS tissue bank after her death. Human tissue is central to studying disease. Studying diseases without human tissue would be a bit like a bricklayer working without bricks.

"It is my mission to get others to donate their tissue to research to help us find new treatments. Sometimes people are shocked that I am so keen to discuss this as it isn't something that people like to think about. But it is important because the doctors really don't know how MS acts on the body; and until they know they can't make progress finding new treatments.

"I think Richard is doing a great job. The tissue bank supplies labs all over the world with tissue to study MS."

In the last year the HTA has helped raise standards by:

- delivering the five key principles of Better Regulation – being transparent, accountable, proportionate, consistent and targeted

- conducting 116 site-visit inspections prioritised on the basis of risk – 51 in the human application sector, 49 in the post mortem sector, 10 in the research sector, 4 in the anatomy sector and 2 in the public display sector
- helping the UK to retain its world class reputation for excellence in biomedical research. We believe that good regulation supports good science, which in turn leads to improved healthcare
- drafting the first code of practice for the research sector to provide guidance and encourage good practice
- holding 12 Regulatory Action Panels to consider significant regulatory action

Enabling more people to benefit from a living-donor transplant

Barbara Ryder, a nurse from Cornwall, donated one of her kidneys to Andy Loudon – someone she had never met before. This type of altruistic donation has been made possible by the systems put in place by the HTA. Barbara and Andy were the UK’s first altruistic donor and recipient to meet. The HTA arranged a press conference where they told their stories to the media.

Barbara Ryder, altruistic kidney donor

“It has been eight months since I became an altruistic donor, and I don’t think about it very often now. I feel even better than I did before, I am feeling really well. If I had another kidney to spare, I would certainly donate again.

“The process set up by the HTA to become an altruistic donor is extremely stringent, but is absolutely necessary to check that you know what is involved. As a nurse I knew from a medical perspective what would happen, but I didn’t truly realise what the donation process would involve. Because it takes a long time, it really gives you chance to think about it. There is no pressure to continue, and you always know that you can drop out if you change your mind.

“I am still in touch with Andy and his wife; we speak about once a month. In fact, they are coming to visit soon and we are planning to go out for dinner. He is very well and it is good to know how he is doing.”

In the last year the HTA has enabled more people to benefit from a living-donor transplant by:

- launching an e-learning course to train new Independent Assessors (IAs). IAs work on behalf of the HTA to make recommendations about whether an organ transplant should go ahead

- approving 997 living donor transplants – including nine altruistic donations and a further 13 novel or complex cases referred to a panel of HTA members. This number is considerably higher than in previous years.
- approving all straightforward organ donations in an average of two working days
- approving 71 reports from Accredited Assessors (AAs). AAs work on behalf of the HTA to make recommendations about bone marrow donations
- supporting IAs and AAs through feedback, regular bulletins, and an annual conference
- holding two media briefing events to raise awareness about the new options for living-donor transplants allowed by the HTA – paired donation and altruistic donation

Ensuring that the wishes of individuals are respected

Iain Johnstone is the Mortuary Manager at the James Paget University Hospital in Norfolk. This is one of 273 organisations licensed by the HTA in which post mortem examinations can take place. In 2008 Iain was given an award by the British Association of Tissue Banks for his work on tissue donation.

Iain Johnstone, Mortuary Manager

"As a Mortuary Manager I have many roles, from working with the families of deceased people, to working with pathologists to help determine the cause of death. My team acts as the voice of the patient and that of their family, ensuring that their wishes are respected.

"We have pioneered a different approach for speaking to families about tissue retrieval. There is never a right time to ask a grieving family to donate tissue, but despite the terrible circumstances, families often readily agree to donate when they realise that their family member can help up to 40 or 50 people who are in need of skin, bone, cartilage, tendons and corneas. This year we won an award from the British Association of Tissue Banks for our work in this area.

"The HTA is important, not just from a legal point of view, but also to translate the law into practice. I am certain that HTA regulation has driven up standards in my field. One of the most important services the HTA offers is guidance and I know there is always someone at the end of the phone or by email to answer technical questions."

In the last year the HTA has ensured that the wishes of individuals are respected by:

- initiating a review of our codes of practice, including the code on consent. The codes provide practical advice to the professionals that we regulate and set out the expected standards. We plan to run a full public consultation on the revised codes in 2008

- working with the Home Office to develop a process and system for the licensing of emergency mortuaries
- evaluating the professional sectors licensed by the HTA to find out their views on how the Human Tissue Act has been implemented. The results of this work showed that, overall, stakeholders are very positive about the HTA. They believe we have had a significant impact and are fulfilling our role successfully

Giving confidence to professionals and the public

Tony Hill is the Director of the Museum of Science and Industry in Manchester, which is licensed by the HTA for public display. The HTA is responsible for licensing organisations that display bodies or tissue from deceased people.

Tony Hill, Manchester Museum of Science and Industry

“I am the Acting Director of the Museum of Science and Industry in Manchester so it is predominantly down to me to choose our exhibitions. Working with human tissue is not something we do every day, so applying for an HTA licence seemed a bit daunting. But the staff at the HTA helped and advised us every step of the way.

“The Body Worlds exhibition is a particularly sensitive one and the process of applying for a licence reassured me, and more importantly our board of trustees, that we had approached the necessary standards with rigour.

“We have had a phenomenal response from the public, with around 130,000 people through the door so far. It is definitely an educational tool and we have tied the exhibition into events on Stop Smoking Day, kidney disease and issues around obesity. We were also giving out cards for the organ donor register and they were so popular we ran out.”

In the last year the HTA has given confidence to professionals and the public by:

- continuing to look for the most efficient and cost effective ways of delivering our remit in order to reduce costs to the licence fee payer and government
- responding to 98% of enquiries within 20 working days
- producing six issues of our e-newsletter which is distributed to 4000 subscribers and provides up-to-date advice and guidance
- holding two Authority meetings in public and an annual report-back event
- working with Ipsos MORI to research what the general public understands about human tissue and its uses, so that we can improve our future communications materials.

Playing a leading role in human tissue regulation in Europe

Ann-Margaret Little works at the Anthony Nolan Trust, which maintains a register of people who have volunteered to donate their bone marrow to help people with diseases like leukaemia. Their bone marrow bank has an HTA licence to ensure the quality and safety of the samples. Justin Adams had been on the Anthony Nolan Trust register for 11 years. Earlier this year, the Trust found a match for his bone marrow.

Ann-Margaret Little, Anthony Nolan Trust

“The Anthony Nolan Trust saves lives thanks to over 390,000 UK residents who have volunteered to donate their bone marrow to any patient in need. We maintain a register of prospective donors, which can be searched to try to find a match for someone who needs a stem cell transplant. We are particularly targeting young adults and those from minority ethnicities to get them to join the register.

“The register has given the chance of life to over 5,000 patients since 1974 and we have always strived for high standards. Now that we are regulated by the HTA this reassures the medical community that we are a professional body, which fulfils criteria set at a national level.

“Regulation has confirmed that we are working in the best way we can. The work of the HTA means that the UK is ahead of many other European countries when it comes to implementing this regulation.”

Justin Adams, bone marrow donor

“I have been on the Anthony Nolan Trust register for 11 years. In October I got a letter and was surprised to find that the Trust had found a match for me.

“I had to go for more tests and I was very aware that someone out there needed my bone marrow and I just wanted to get on with it. But everyone was very nice and helpful; they were keen to make sure I really understood what would happen. It is good to know that this area is regulated, it's important that someone is checking that there is no bad practice.

“My bone marrow went to help a young boy, but I don't know anything else about him. I want everyone to know that the process is not very painful.

I would gladly do it again and I would recommend it to anyone. It's such a simple way to give someone the chance to live. I can think of no good enough reason to justify not becoming a donor.”

In the last year the HTA has played a leading role in human tissue regulation in Europe by:

- licensing organisations that procure, process, test, distribute, and import or export human tissue for use in patient treatment under the EU Tissue and Cells Directive. The Directive has been brought into UK law through Quality and Safety Regulations, which have set a

benchmark for the quality and safety of human tissue and cells across Europe

- developing an online system for establishments in the human application sector to report adverse events
- publishing a code of practice on the import and export of human tissues and cells
- holding an international conference for professionals working in the human application sector to share their experiences
- holding two workshops for procurement organisations to help us develop our regulatory policy arising from the Quality and Safety Regulations

Improving training for the health professionals of the future

David Yu is an Anatomy Demonstrator at Brighton and Sussex Medical School. Human bodies are used to teach medical students about the structure of the body and how it works, and to train surgeons on different surgical procedures. Organisations like Brighton and Sussex Medical School, which carry out these activities, are licensed by the HTA.

David Yu, Anatomy Demonstrator

“I am an Anatomy Demonstrator at Brighton and Sussex Medical School. We use whole body dissection to help teach our students, it is an important part of their medical training alongside lectures and going into a clinical setting. With whole body dissection students get a much better understanding of how each organ relates to the others.

“It is essential that people realise what a central role dissection plays in teaching the doctors of the future. It isn't just medical students who benefit – we now have surgeons coming in to develop new techniques on real bodies. This is a good thing, as it is important for surgeons to develop their techniques in the dissection room before going into the operating theatre. Recently we also had mechanical engineers come in to take measurements to help develop new types of prosthetic joints.

“Regulation by the HTA is important as this reassures the public that bodies that are being used for educational purposes are treated with respect.”

In the last year the HTA has improved training for health professionals by:

- launching an e-learning course to provide continuing support and training the people in licensed establishments, including Designated Individuals (DIs)
- holding eight training workshops for DIs

- providing advice to people who want to donate their body to medical science and a list of local medical schools on our website
- starting a project to review the data collected from the anatomy sector and the HTA anatomy forms

The year ahead

During the year ahead we plan to continue to build the confidence of professionals and the public by:

- completing the review of our codes of practice and undertaking a full public consultation
- holding a series of workshops and events to develop further our regulatory methods
- delivering a programme of consistent, targeted advice and guidance across the sectors
- undertaking a risk-based programme of site visit inspections across the five licensed sectors
- continuing to implement the requirements of EU legislation, including licensing organisations that carry out procurement
- managing the live organ and bone marrow transplant approval programme
- working with other organisations to streamline regulation
- developing a proportionate fee structure for 2009
- answering all enquiries in a timely, appropriate and accurate manner
- launching a guide to our key messages to help others communicate with the public about our work

Back cover text

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Agenda item	11	Author	Peter Lemmey

Codes revision: consultation arrangements

Introduction

1. This paper sets out the arrangements for public consultation on the HTA's revised codes of practice. It is for Members' information.

Background

2. The Authority's codes of practice are statutory documents and as such require Parliamentary approval. Formal consultation of the public on the codes in draft is an important step towards the Authority's approving a final version of the documents for submission to Ministers and Parliament. The process for public consultation is governed by guidance from the Cabinet Office and the Better Regulation Executive.
3. Our experience from consulting on the Authority's first set of codes in 2005 indicated that stakeholders may at the consultation stage provide valuable advice and insights which serve to

refine the draft codes, while the Authority may also use consultation to emphasise its commitment to engagement and openness with its regulated sectors as well as with a wider public.

Timing of public consultation

4. The codes revision programme board plans to start public consultation on the draft codes on 1 August 2008. Cabinet Office guidance suggests a minimum period of three months for consultation on policy: in view of the summer holiday period, we propose to consult for fifteen weeks in all, with the consultation period finishing on 14 November.
5. Analysis of the responses will be done in late November/December, with the Authority considering the outcome of consultation and final post-consultation versions of the codes in the New Year. We aim to have the final revised set of eight codes ready for Ministerial and Parliamentary approval by the end of March.
6. In planning the public consultation on the revised codes, we intend to base our approach on the way we consulted on the first set in 2005. We will put the draft texts up on the Consultation section of the website and invite comments (preferably by e-mail) on general style, fitness for purpose, on clarity and how we have distinguished between statutory requirement and good practice, and on the various policy topics which the Authority and members' policy group have highlighted during the drafting process. Our stakeholders will be alerted to the opportunity to comment before formal consultation starts. Last time round, Members helped the executive to summarise and prioritise the 100+ database pages of responses, and we would hope for similar input this time; responses are unlikely to be fewer.

Consultation workshops

7. Consultation workshops have proved a useful way of resolving policy issues within codes of practice - the Public Display workshop was a case in point - and they also provide tangible evidence of the HTA's openness in dealings with stakeholders. We have also found them a useful forum where stakeholders can exchange views about the Authority's advice and guidance.
8. We intend to arrange a number of consultation workshops, to be held during October. Likely workshop topics include the new research code; and the consent, PM and disposal codes taken together, with a focus on retention and disposal of tissue. Members' input was a positive feature of previous consultation workshops and we hope it will again be so in the autumn.

Recommendation

9. Members are invited to note the contents of this report, and in particular the proposals for Members' involvement in the consultation workshops and the analysis of consultation responses.

