

Summary of compliance 2008/09

Regulating the anatomy sector

Working together to drive up standards

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Introduction

1. In September 2008, the HTA published a set of five summary inspection reports; one relating to each of our licensed sectors. The reports provided an overview of how the sectors complied with HTA licensing standards and summarised the key learning points from a range of information that we held about our licensed establishments. The anatomy report covered the period 1 September 2006 to 31 March 2008. It is available on our website at: www.hta.gov.uk/db/documents/HTA-inspection-anatomy-v3.pdf.
2. The aim of this report is to provide an overview of the period 1 April 2008 to 31 March 2009, including:
 - any changes to the number of anatomy establishments
 - an update on the sector's compliance with our standards
 - a summary of the regulatory action we took
 - learning from inspections
 - a summary of some of the advice and guidance we gave, and
 - an overview of sector-specific policies which we developed

What did we report last time?

3. During the period 1 September 2006 to 31 March 2008, the HTA received 45 applications from establishments in the anatomy sector. Of these, 24 were for stand-alone establishments and eight were for hubs that altogether had a total of 13 satellite sites attached. The majority (28 or 62%) of establishments were medical schools on university premises. We imposed 15 conditions across seven establishments following phase 1 desk-based inspections of the 45 applications.
4. We undertook four phase 2 site-visit inspections. As a result, we imposed one additional condition and provided a total of 23 individual items of advice and guidance. The majority of advice and guidance related to our governance and quality systems standards (GQS); specifically, the implementation of documented systems of quality management.

What changes have there been to the profile of the anatomy sector since 1 April 2008?

5. The number of anatomy establishments has changed very little. During 2008/09, only one new licence application was submitted. This was for a newly built site that replaced an older teaching hospital site. One additional condition was placed on the licence at the initial application stage, requesting that a documented disposal policy be put in place. One licence for a satellite site was archived during this period as it is no longer undertaking licensable activities.
6. As stated in last year's report, all anatomy establishments met at least the minimum level of compliance with HTA standards and many demonstrated that they had good, and sometimes exemplary, systems and processes to support licensable activities. However, we know from phase 2 site-visit inspections that there are still some establishments that have not fully implemented quality management systems. Further, based on an analysis of queries we received from individuals working at licensed anatomy establishments, we know that there is still some uncertainty about what constitutes valid consent.

What did we find during phase 2 site-visit inspections undertaken between 1 April 2008 and 31 March 2009?

7. During this period, we undertook four phase 2 site-visit inspections, imposed four additional conditions and gave 23 individual items of advice and guidance. All four conditions related to one licensed establishment.

Learning points for Designated Individuals (DIs): conditions

What led to the four conditions being imposed?

- lack of an adverse event reporting system
- lack of formalin level monitoring
- lack of safe, secure storage for records
- lack of documented cleaning and equipment maintenance schedule

8. Most of the advice and guidance we gave during 2008/09, as with that given between 1 September 2006 and 31 March 2008, related to a lack of documented quality management systems. On one hand, the consistency in our findings is not surprising as we know that quality management is a concept the sector has historically been unfamiliar with. On the other, it indicates that not all DIs have improved their systems and processes in line with the advice and guidance we gave in the last report.
9. Table 1 compares the distribution of advice and guidance given, following the four phase 2 site-visit inspections reported on previously, with that following the four inspections we undertook during 2008/09.

Table 1: Distribution of advice and guidance following phase 2 site-visit inspection, grouped by category of standard

	Consent	Governance and quality systems	Premises, facilities and equipment	Disposal	Totals
Items of advice and guidance given between 1 September 2006 – 31 March 2008	1	14	8	0	23
Number of establishments affected	1	3	4	0	*4
Items of advice and guidance given between 1 April 2008 – 31 March 2009	2	16	3	2	*23
Number of establishments affected	2	4	3	2	4

*actual number of establishments affected. Establishments may have more than one condition imposed and be offered more than one item of advice and guidance.

10. Coincidentally, we gave an identical number of items of advice and guidance between 1 September 2006 and 31 March 2008 as we did during 2008/09. However, the distribution of advice and guidance changed slightly. In the latter period we advised on matters relating to disposal during two of the four inspections, whereas we did not need to offer any at

Learning point for DIs: disposal

It is advisable that, if you have not done so already, you undertake an audit to ensure that you are not storing any specimens that are no longer fit for the purpose of anatomical examination or teaching. If you are storing specimens that are not intended for use i.e. they are being stored without a purpose, you should dispose of the specimens, documenting the reason and method of disposal.

11. Notably, we gave almost three times more advice and guidance relating to premises, facilities and equipment (PFE) during the first four inspections as we did during those undertaken in 2008/09. This may be an indication that DIs have generally invested time and resources in ensuring that the premises are fit for purpose. They have achieved this by, for example, ensuring that dissecting rooms are decluttered as far as is practical, that there are suitable storage facilities for specimens and that the environment is appropriately monitored.
12. Paragraphs 7–11 cover our broad findings. The following two paragraphs break down our findings further by focusing on how much advice and guidance we have given relating to the implementation of standard operating procedures (SOPs) and the undertaking of risk assessments. The reason is that both the previously mentioned aspects of a quality management system are the areas that establishments universally find difficult to fully implement.
13. Although the advice and guidance we gave during 2008/09 was similar in nature to that which we offered between 1 September 2006 and 31 March 2008, we offered over 50% more advice and guidance relating to SOPs and risk assessments. If we assume these findings are representative of the sector as a whole, this demonstrates that although establishments generally have procedures supporting the work they undertake, they can still be improved. Also, risk assessments of all critical processes associated with the licensable activities are still not routinely being undertaken.

Learning points for DIs: SOPs and risk assessments

We recommend that, if you have not done so already, you consider whether the following advice and guidance is relevant to your establishment:

1. Each policy and procedure document has:
 - i. document control information, such as a revision history and version number
 - ii. pagination; and
 - iii. the names of both the author and the person who authorises the document
2. All risk assessments of critical procedures such as cadaver receipt and disposal are reviewed in addition to all necessary health and safety risk assessments
3. Regular meetings for all staff working under the licence take place where matters such as adverse events, changes to SOPs, audits and risk assessments can be discussed

14. Two of the four phase 2 site-visit inspections we undertook during 1 September 2006 and 31 March 2008 were in direct response to adverse events, whereas this applied to only one of the four inspections undertaken during 2008/09. The decision to inspect was taken during the one Regulatory Action Panel (RAP) linked to an anatomy establishment, which was convened in order to ensure that all relevant considerations were taken into account and the control measures that we implemented were fair, proportionate and justifiable.

15. The event related to a body part that was not fully incinerated, which led to closure of an incineration plant while an investigation was undertaken. Staff at the plant had not been made aware of the body part by their colleagues and were therefore not able to apply necessary measures to incinerate it. The body part had originated from a HTA licensed anatomy establishment. Due to the efficacy of traceability systems at the establishment, the origin of the body part was quickly identified and the plant was reopened. Learning from the incident was shared with the anatomy sector in the form of a position statement and frequently asked questions (FAQs) which are available on our website:

www.hta.gov.uk/legislationpoliciesandcodesofpractice/faqsonthe disposalof anatomicalspecimensformeranatomicalspecimensandbodyparts.cfm

16. The DI was required to produce an incident report and action plan, which highlighted any procedural areas for improvement and how these would be communicated with staff working under the licence. This was an isolated incident and no related concerns were identified during the subsequent site-visit inspection that was scheduled with the DI.

What do the enquiries we receive tell us and what learning can be drawn from them?

17. During 2008/09, we received a steady flow of enquiries from staff working in anatomy establishments about a variety of matters including the validity of consent, the making and use of images, disposal and the transfer of material between establishments.

18. In the last report, we advised DIs to review their protocols and SOPs for receiving cadavers to ensure that they covered as many scenarios as possible, with a particular focus on what constitutes valid consent.

19. The majority of enquiries we receive about consent are from people working at licensed establishments, who want a second opinion from the HTA about whether donor consent is valid or not in specific circumstances. We recognise that validation is sought as the anatomy sector as a whole wants to ensure it complies with legislative requirements. Although we do not want to discourage people from seeking our advice, we have laid out some guiding principles governing valid consent, which we hope is helpful.

Learning points for DIs:

What are the guiding principles governing valid consent?

For consent obtained before the implementation of the Human Tissue Act 2004 (HT Act) on 1 September 2006, DIs should continue to judge any ambiguous donation on a case-by-case basis, giving consideration to the consent framework in place at the time of donation. Most commonly, consent would have been under the Anatomy Act 1984 (Anatomy Act).

If a person expressed a request in accordance with section 4(1) of the Anatomy Act that their body be used for anatomical examination and the person died after the HT Act came into force (1 September 2006), then the request under the Anatomy Act is treated as appropriate consent under section 1 of the HT Act.

The Anatomy Act required the person to express a request either:

1. in writing at any time; or
2. orally in the presence of two or more witnesses during his their last illness, that their body be used after death for anatomical examination

For consent obtained after the HT Act came into force, it is essential that the consent is valid and specifically declares that the deceased wished to donate their body for 'anatomical examination'. The HT Act makes a distinction between the scheduled purpose of 'research' and that of 'anatomical examination'. It is not sufficient for donors to donate their body to 'research' or 'medical research' and be accepted for anatomical examination on that basis.

If a UK citizen resides abroad and dies abroad they can not donate to a UK establishment as the requirement of section 1(2) and (3) of the HT Act would not be met as registration of death would not be under the Births and Deaths Registration Act 1953.

What policy developments were there between 1 April 2008 and 31 March 2009?

20. As well as developing and implementing a continuous licensing system, and producing an updated code of practice on anatomical examination, we worked on several policy matters specific to the anatomy sector. These have been communicated via our e-newsletters, available on our website: www.hta.gov.uk/newsandevents/e-newsletter.cfm
21. In order to ensure that the sector as a whole has been represented in the development of policy, where it has been appropriate to do so we have liaised with the Professional Guidelines and Practices (Anatomy) Committee.
22. In December 2008, in order to reduce unnecessary data collection, we announced that we would no longer require establishments to report cadaver acceptance and disposal information to us via the online submission system. In addition, in response to a number of enquiries, we revised our template form for body donation and launched a new template form for the loan of specimens to unlicensed premises. The loan form should be completed by the DI at the licensed establishment, to give authorisation for the loan of specimens to an unlicensed establishment. However, so that loans can occur in the absence of the DI – providing they have put in place systems and processes to ensure that the criteria for agreeing loans and the processes governing loaning are consistent – a Person Designated (PD) can authorise the loan. This delegation of responsibility should be formally recorded.
23. In April 2009, following several interactions with staff at anatomy establishments, and subsequent dialogue with the Ministry of Justice (MoJ), we offered advice about the Cremation Regulations 2008 and the amended forms to support the cremation process. The old Form A has been replaced by the form Cremation 1, which is available from the MoJ website: www.justice.gov.uk/guidance/cremation.htm.
24. For body donations that pre-date the new form, the Cremation 1 form should be completed by the DI and submitted alongside Form A, which will have been completed by the donor's family. The ultimate decision to accept such an arrangement rests with the medical referee at the crematorium; however, we have been advised by the MoJ that they do not foresee any problem with this approach.

25. In June 2009, in response to requests for specific guidance about the types of relevant material which can be incinerated or cremated, we produced a position statement on the disposal of anatomical specimens, former anatomical specimens and body parts (including those which have been imported) and a series of frequently asked questions (FAQs) on the issue. Also, in recognition that the import of fresh frozen bodies and body parts is emerging as a potentially common practice for some HTA-licensed establishments, we produced a position statement on the import of fresh frozen bodies and body parts, which is derived from our policy on the import of fresh frozen bodies and body parts. The policy includes the HTA's expectations of the responsibilities of establishments that import or export fresh frozen cadaveric material. All the information referred to in this paragraph can be accessed via our website at:
www.hta.gov.uk/legislationpoliciesandcodesofpractice/policyontheimportoffreshfrozenbodiesandbodyparts.cfm and
www.hta.gov.uk/legislationpoliciesandcodesofpractice/positionstatementontheimportoffreshfrozenbodiesandbodyparts.cfm.
26. The development of policies demonstrates our commitment to responding to enquiries and feedback from the anatomy sector. If you feel that there are areas of policy development that are within the HTA's remit which still need to be addressed, you can email Christopher Birkett at christopher.birkett@hta.gov.uk.

What next?

27. Throughout the 2009/10 business year, the HTA plans to work with DIs, Licence Holders and PDs from the anatomy sector to help increase compliance with our governance and quality systems standards.
28. We also plan to run another stakeholder training event before April 2010. The event, which will be advertised in our e-newsletters and on our website, may also be supplemented by 'hot topics' in e-newsletters, which focus on the implementation of quality management systems.
29. We will continue to liaise with the Professional Guidelines and Practices (Anatomy) Committee on any matters of mutual interest, and will continue to respond to enquires from the sector. We will carry on identifying trends and themes arising from enquiries and summarising learning points that can be shared.
30. We hope this report has been useful for you. If you have any suggestions for how we can improve the format and content of our reports, you can email christopher.birkett@hta.gov.uk.

Appendix 1: List of establishments that received an HTA phase 2 site-visit inspection in 2008/09

- St. George's University of London, Division of Basic Medical Sciences (Anatomy)
- The Royal College of Surgeons of England
- Imperial College London, Department of Psychological Medicine, Burlington Danes Building
- University of Northumbria at Newcastle (School of Applied Sciences)

Details of all licensed establishments are listed on the HTA website:
www.hta.gov.uk/licensing/licensed_establishments.cfm.

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Published in October 2009