

Summary of inspections 2006–2008

Anatomy

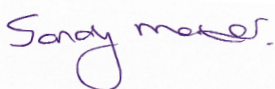
Foreword

This summary inspection report is one of a set of five that the Human Tissue Authority (HTA) has produced for each of the sectors that we license and inspect: anatomy, human application, post-mortem, public display and research. The reports summarise the key learning points from a range of information that we hold about the establishments that we regulate. They are vital reading for anyone who works in these sectors, so that lessons may be learnt and standards improved.

The HTA's regulatory methods are framed by the requirements of the Human Tissue Act 2004 (HT Act) which places a specific obligation on the HTA to follow the principles of Better Regulation and to carry out regulatory activities in a way that is transparent, accountable, proportionate, consistent and targeted. The proportionate, risk-based regulatory system that we use is also informed by the good practice from key Government reports: Reducing administrative burdens: effective inspection and enforcement (Philip Hampton, 2005) and Regulation – less is more, reducing burdens, improving outcomes (Better Regulation Task Force, 2005). In April 2008 the statutory code of practice for regulators (the Regulators' Compliance Code) came into force. This provides further guidance on Better Regulation and will form the basis of an external inspection of the HTA's regulatory systems by the Better Regulation Executive during the 2008/09 business year.

The HTA works with those who need to be licensed by acting as “coach” not “cop” to bring them into the licensing framework, and to provide advice and guidance to help them to improve standards. This compliance-based approach to regulation is partnered with the HTA's proportionate approach to enforcement, which is aimed at deterring future non-compliance.

These summary inspection reports are the next steps on the path to improving standards for the regulation of human tissue. We hope that all those working in the sectors we license and inspect will review this information, and reflect on how it could be applied to their own practice to improve standards.



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Executive summary

In the period 1 September 2006 to 31 March 2008 we licensed 45 anatomy establishments and carried out 4 site visit inspections.

We applied 15 conditions across seven establishments following phase 1 desk based inspection, a further one following a phase 2 site visit inspection and offered a total of 23 individual pieces of advice and guidance.

The anatomy sector has generally embraced the changes brought about by the HT Act and practices and processes have been adapted in order to work towards compliance with HTA standards.

We found that the main areas of weakness in this sector are in governance and quality systems, and the management of adverse events. The majority of deficiencies were a consequence of an informal approach to managing quality which appears to be due to a lack of familiarity with concepts such as governance and quality management. This was shown by: the absence of some critical Standard Operating Procedures (SOPs), the absence of procedures ensuring staff adhere to SOPs, an unstructured approach to audit and ineffective management of adverse events and risk assessments.

Two adverse events were reported to us, both of which were dealt with appropriately and professionally by staff working at the establishments. This is a reflection of individual and organisational respect for the gift of body donation and the genuine commitment to maintaining the dignity of the deceased.

Introduction

1. This summary inspection report is one of a set of five. Each report is specific to one of the sectors we license and inspect. The findings in the report are drawn from two main sources of existing knowledge that are held by HTA.
 - information and data submitted by an establishment (i.e. as part of the compliance report licence application process and during the site visit inspection process)
 - documents that we have issued to establishments (i.e. drawn from site visit inspection reports and licensing decisions)
2. This report brings all the information together in one place and provides an analysis of trends and themes for the anatomy sector so that lessons can be learnt. The individual site visit inspection reports and proposed licensing decisions have each been reviewed by the Designated Individual (DI) responsible for supervising licensable activities in the establishment concerned. In accordance with statutory requirements, the HTA gives each Licence Holder (LH) and DI clear reasons for proposed licensing decisions and gives the establishment the opportunity to make representations about a proposal to add conditions before the HTA makes the final licensing decision. In this way, the HTA demonstrates transparency about the judgements and licensing decisions that have been made and the reasons for them. In addition, all individual licensing decisions made as a result of the findings included in inspection reports have been carefully considered with input from legal advisors and, where appropriate, a senior member of the regulation directorate. This summary report therefore draws on a wide range of pre-existing information and data that are currently held by the HTA. It is intended to provide a review and analysis of the findings from the anatomy sector so that the reader may consider them and, where appropriate, apply them to their own practice to enable standards to be raised across the sector.

Introduction (continued)

3. It is important to note that the conditions and advice and guidance the HTA gives to an establishment are context-specific, and do not always lend themselves to be easily or appropriately transferred to another licensed establishment. Each licensing decision the HTA makes is specific to the facts of the case and only relevant information is considered. The HTA exercises its discretion reasonably and aims to make regulatory decisions that are transparent, accountable, proportionate, consistent and targeted where action is needed. Therefore we do not routinely apply the same decision to each establishment. This means that while the HTA aims to be consistent in its decision making process, decisions will vary from establishment to establishment depending on the particular set of circumstances. So, the conditions and advice and guidance are context specific and are not always transferable to other establishments. They should be read with this in mind.

Using a risk-based regulatory approach

4. The HTA uses a risk-based regulatory approach to inform how we prioritise the phase 2 site visit inspections (see Appendix 1 for more information about the inspection process). Risk means different things to different people, according to context. So it is relevant at this point to explain what we mean by risk when referring to how we regulate. In this context, the risk the HTA refers to is regulatory risk, i.e. the risk of non-compliance with the requirements of the legislation that the HTA was set up to implement. The primary documents that inform the framework for regulatory risk are: the HT Act and the associated Regulations, including for the human application sector, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). These are therefore mandatory requirements. The legislation is supported by other documents that are developed by the HTA. Where possible, we develop this additional guidance with input from those we regulate. These documents include: codes of practice, Directions, and licensing standards.

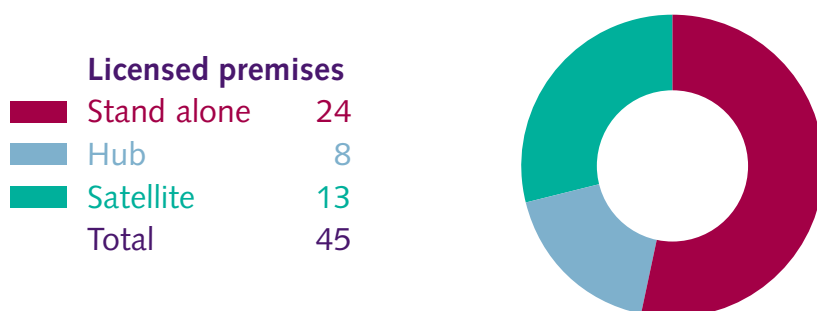
Introduction (continued)

5. We bring the core elements of the legislation and other documents together in the licensing standards that form the basis of the compliance report licence application for each sector. The specificity and detail of regulation required for each sector is set out in the relevant legislation. Some sectors have much more detailed requirements than others. Generally, the detail of standards and requirements increase when there is a direct risk to patient safety if they are not met. The corollary is that where there are more standards with greater specificity, there is an increased risk they will not be met. Therefore the HTA focuses resources on where this is most likely to occur so that advice and guidance can be offered to help professionals achieve regulatory compliance. This means the regulatory risk of the sectors we license and inspect varies from low risk, where there is minimal regulation and a lighter touch approach can be used, to high risk, where there is detailed regulation with specific requirements and a more direct regulatory approach is employed.

Overview of anatomy sector and inspections 2006–2008

6. There are 45 anatomy premises within our licensing framework, grouped as follows:

Figure 1: The number of stand alone establishments, hubs and satellites



7. During the period 1 September 2006 to 31 March 2008, the HTA licensed a total of 45 anatomy premises. Of these, eight are hub establishments as they have satellite sites attached. A satellite is a smaller establishment with its own licences which is normally engaged in the same licensable activities and operates under the same governance as the hub. 24 of the 45 anatomy establishments have no satellites attached and are referred to as stand alone establishments.
8. All establishments received a phase 1 inspection (see Appendix 1 for more information on our inspection process).
9. During the same period we held one Regulatory Action Panel (RAP) in the anatomy sector which resulted in the HTA issuing Special Directions.
10. The majority of establishments are medical schools which are on university premises. Medical schools were regulated under the Anatomy Act 1984 prior to the commencement of the HT Act.

Overview of anatomy sector and inspections 2006–2008 (continued)

11. The donation of bodies (also referred to as cadavers in this report) is consented by the donor under the HT Act and their consent must be written and witnessed. Licensed anatomy establishments should have systems and processes in place to advise members of the public of their specific requirements. Members of the public who would like to donate their body to medical science, should speak to bequeathal staff as they usually manage this process. There is a list of licensed anatomy establishments on the HTA website:
www.hta.gov.uk/licensing/licensed_establishments.cfm
12. Early in the development of our licensing and inspection methods we worked with representatives from the anatomy sector. During late 2006 and early 2007, we undertook two pilot site visit inspections of anatomy establishments which helped to develop our approach and guidance for inspections.
13. Two of the four site visit inspections we carried out were in direct response to adverse events. One of the inspections was unannounced which resulted in the HTA issuing Special Directions, requiring the DI to take immediate action relating to unsuitable practices. More detail about the adverse events is contained in paragraphs 22 and 28 of this report.

Analysis of additional conditions, and advice and guidance

Table 1: Distribution of additional conditions, and advice and guidance following phase 2 inspection, grouped by category of standard

	Consent	Governance and quality systems	Premises, facilities and equipment	Disposal	Totals
No of standards	3	7	5	2	17
No of additional conditions applied at phase 1 inspection	4	7	2	2	15
No of establishments affected	3	4	1	2	N/A*
No of additional conditions applied at phase 2 inspection	0	1	0	0	1
No of establishments affected	0	1	0	0	1
No of items of advice and guidance	1	14	8	0	23
No of establishments affected	1	3	3	0	N/A*

***NB:** An establishment may have a condition against more than one category of standards (e.g. a condition relating to consent and a condition relating to governance and quality systems). Such establishments have been included in the figures more than once (i.e. an establishment with conditions relating to consent and governance and quality systems will be included in the figures for consent and governance *and* quality systems).

Analysis of additional conditions, and advice and guidance (continued)

14. We applied 15 time-bound additional conditions to the licences of seven anatomy establishments following a phase 1 desk based inspection. We only applied one further condition following phase 2 site visit inspection.
15. Overall, anatomy establishments demonstrated least compliance at phase 1 inspection with our standards on governance and quality systems. Four of the 15 conditions were linked to standard GQ2, showing that the most deficient area related to a lack of documented systems of quality management and audit. Our findings on phase 2 site visits support our findings from phase 1 as we offered a total of 23 items of advice and guidance, the highest number of which was linked to standard GQ2.
16. When reading the following sections of this report, it is important to bear in mind that although the findings from phase 2 inspections have been included, the focus of the report is the findings from the phase 1 inspection process.

Compliance with HTA standards

Consent standards (C1–C3)

Key findings

17. The vast majority of anatomy establishments demonstrated that they met our standards on consent so that consent is obtained in accordance with the HT Act and codes of practice. We applied four conditions to licences and issued one item of advice and guidance.
18. In addition to providing advice and guidance during site visit inspections, we have advised staff working in the anatomy sector on matters ranging from whether a body can be accepted where consent was given under the Anatomy Act, to whether the paperwork that they are in receipt of sufficiently demonstrates that the death certificate has been signed and the death has been registered. We advise that establishments review their protocols and SOPs for receiving cadavers to ensure that they cover as many scenarios as possible, to allow staff to make safe and reasoned decisions.

C1 Consent is obtained in accordance with the requirements of the HT Act 2004 and as set out in the code of practice

19. When a member of the public is considering donating their body, they contact their local medical school and usually speak to a member of the bequeathal team. They are generally then sent a pack of information to enable them to make an informed choice about whether to proceed with the donation. If they decide to donate, they fill in a consent form which they sign, and it is counter signed in the presence of a witness who attests their signature. Most medical schools have their own bequeathal team, although in some instances the bequeathal process is managed by a central team acting on behalf of a number of establishments. The central team in this case would be known as the 'third party'.

Consent standards (C1–C3) (continued)

20. Under the previous legislation, the donor did not need to give their consent to donation and the family members were able to consent on behalf of their deceased relative. The implementation of the HT Act has therefore brought about a significant change in the donation process as now only the donor can consent. We found that the vast majority of anatomy establishments managed this effectively by amending their donor information packs to reflect the legislative changes. The HTA provided a model consent form, which many establishments have tailored according to their local protocols and procedures.
21. We applied conditions related to this standard to the licences of two establishments. In each case, we required the DI to implement a formal agreement with third parties managing the donation process on their behalf, as it was not clear from the written evidence provided to HTA that the DI could be assured that consent was obtained in accordance with the requirements of the HT Act and codes of practice.
22. The HTA undertook a reactive site visit inspection following notification of an adverse event which involved the distribution of consent forms that were not compliant with the HT Act. The DI reported the event to the HTA as soon as they became aware of it and immediately addressed the situation. On inspection we found that the event was attributable to the establishment's own SOP not being followed. However, the DI took sufficient steps to rectify the situation and put measures in place to ensure that non-compliant consent forms were no longer distributed.

Consent standards (C1–C3) (continued)

C2 Information about the consent process is provided and in a variety of formats

23. We found that all licensed anatomy establishments provided adequate information about the consent process. The HTA has provided advice and guidance about bequeathal and published a generic information booklet on our website for all DIs to use as appropriate. Some DIs have tailored the booklet and sent it in conjunction with letters to potential donors. The letters explain, for example, the process that occurs following death, the time over which an anatomical examination may take place and what happens if the donor consents to the retention of body parts. A large proportion of establishments demonstrated that they provided information in a number of different languages as well as in a variety of formats by, for example, using large print or making it available verbally on a CD. We found that medical schools often encouraged potential donors to contact them to seek information about the process of donation and how their body would be used for the purpose of anatomical examination.

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent

24. We found that all but one anatomy establishment provided training to relevant staff (usually bequeathal secretaries) about the consent process. Where training was not in place, we required the DI to ensure that staff received initial training and ongoing support in the process to ensure that they were obtaining consent in accordance with the requirements of the HT Act and relevant codes of practice. We also required the DI to document the training. This condition was followed up on site visit inspection. The additional information gathered demonstrated that the establishment complied with this standard. We advised that the DI maintains a record of suitably qualified staff who manage the consent process and that the staff sign to state they had read, understood and would adhere to the HTA codes of practice on Consent and Anatomical examination.

Governance and quality systems standards (GQ1–GQ7)

Key findings

25. The vast majority of establishments had effective systems governing the undertaking of anatomical examinations and the storage of specimens and former anatomical specimens. We applied eight conditions to licences and issued 14 items of advice and guidance. The most common area of non-compliance across all the governance and quality standards (and in fact all HTA standards), related to quality management and audit systems. We also offered most advice and guidance about these standards.
26. Some common areas identified for improvement related to:
- the absence of a quality manual incorporating an audit schedule and document control system
 - a lack of SOPs for all critical processes, e.g. the management of adverse events
 - a lack of opportunity for collaborative working between technical and administrative staff
 - a lack of understanding about what needs to be risk assessed in addition to health and safety assessments

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process

27. Anatomy establishments are predominantly based on university campuses. In most cases, the university as the holder of the licence is represented by a member of senior management. On the whole, lines of accountability are clearly structured and the vast majority of anatomy establishments have effective governance systems in place.

Governance and quality systems standards (GQ1–GQ7) (continued)

28. We undertook an unannounced inspection in response to an adverse event resulting in the dignity of the deceased being compromised. As with the adverse event referred to in the section on consent (C1), the event was partly a consequence of internal processes not being followed. The event was also due to the lack of SOPs in some areas. By giving Special Directions, we required the DI to put in place immediate measures to ensure that students in the medical school were adequately supervised at all times and that they did not enter the dissecting room without prior arrangement and registering their attendance. We followed up the unannounced inspection with a scheduled site visit inspection. We found that all the requirements of the Special Directions had been met and no further conditions were applied to the establishment's licences. We did, however, offer the DI some advice and guidance suggesting that consideration was given to establishing SOPs for some critical processes, such as cleaning and decontamination procedures.
29. We recommend that as well as out-of-hours student access to the dissecting room being pre-arranged and supervised where possible, DIs set up systems to make sure that students sign in and out, record the purpose of their visit and the person under whose supervision their access is permitted. This will assist DIs in tracing back to see which students were on the premises at any given time and reduce the risk of unsuitable practices taking place.
30. The HTA has found that technical staff, e.g. prosectors working in anatomy establishments work quite autonomously and in some cases such staff do not have daily contact with bequeathal staff working in a separate part of the building. The risk is that different staff do not have the opportunity to discuss, identify and address areas for improvement. DIs should ensure that communication is open and information is disseminated to all appropriate staff in a consistent manner, e.g. by distributing staff meeting minutes and HTA e-newsletters.

Governance and quality systems standards (GQ1–GQ7) (continued)

GQ2 There is a documented system of quality management and audit

31. This was the area in most need of attention, as some systems had not been implemented and some were embryonic and in need of development. We found that on the whole the sector was not familiar with the concept of quality management although many aspects were incorporated in their practices but these were followed in an informal and sometimes unstructured way.
32. Quality management underpins the effectiveness of a service, focussing on the essential processes within an organisation and the commitment to further develop these processes. To ensure the development of these processes, the organisation needs to identify areas for improvement and manage any changes required to address them.
33. A key component of managing quality is undertaking regular audits. Depending on the scale of activity taking place at anatomy establishments, there needs to be some form of quality management to ensure that DIs oversee the storage of bodies, specimens and former anatomical specimens to facilitate traceability and to ensure that anatomical examinations are carried out in accordance with professional guidelines, local protocols and SOPs.
34. Audits of records can assess completeness, legibility and accuracy. An audit of records could compare the content of electronic and paper databases. Audits of processes may include looking at individual procedures from cadaver receipt to burial or cremation to confirm that SOPs are being followed and that they reflect current practice. This may also include an audit of specimens to ensure that the record of prosecutions retained following the disposal of the body matches the collection held. The outcome of audits and any follow up action should be documented and shared with staff. The HTA advises that the audit schedule is referenced in, or incorporated into, the quality manual.

Governance and quality systems standards (GQ1–GQ7) (continued)

35. This standard generated the highest level of conditions at phase 1 and the most advice and guidance at phase 2. Areas of non-compliance included:
- the absence of SOPs setting out how to manage complaints and how to report, manage and analyse adverse events
 - the absence of procedures for ensuring that staff were working to current SOPs
 - no schedule of regular internal audits to check the legibility and accuracy of records
36. We offered advice and guidance to three out of four establishments that we visited about how to improve their systems of quality management and audit. We recommend that other DIs consider whether the advice is applicable in the context in which they work. Before doing so, however, DIs should be aware that the HTA advises that establishments keep their quality management system proportionate to the size and activity of the establishment and the number of staff, concentrating on making the system manageable, functional and useful.
37. Where we found that quality management systems needed improving, we advised DIs to develop a quality manual. The manual should be accessible to all members of staff and give a practical overview of the establishment's activities, and provide a summary of the structure and working practices. It should act as a resource, referencing policies and SOPs. The quality manual could be in paper or electronic format but should be backed up to prevent loss of information. The manual could cover a general outline of the activities taking place at the establishment including: sections setting out the main responsibilities of the establishment, the staffing structure and lines of accountability, and an overview of current arrangements from body donations through to memorial or thanksgiving services where they occur. The manual could also demonstrate intent to conform to the requirements of regulatory and professional bodies by, for example, detailing relevant governance meetings. It could also reference staff training and appraisal processes and human resources documents such as grievance procedures, complaints procedures and disciplinary procedures.

Governance and quality systems standards (GQ1–GQ7) *(continued)*

38. The HTA found that the risk of adverse events occurring increases when staff do not adhere to SOPs. It is therefore important that DIs make sure that up-to-date SOPs are followed. In order to facilitate this we advised some DIs to implement a document control system that included:

- a unique identifier for all documents
- the identification of the author of a document
- the identification of the owner of a document
- the version number of the document
- the issue date of a document
- page numbers

39. Where possible, the HTA advises DIs to consider sending staff the intranet link to all new policies and procedures to discourage them from using printed copies, minimising the risk of them referring to outdated documents.

40. **Scenario** – this scenario draws on good practice that we have seen at phase 1 and 2 of the inspection process. It also reflects the process that the HTA follows when undertaking a traceability audit on site. The HTA hopes that it will help DIs when they are considering how to drive up standards in their establishments.

A DI has put in place a schedule of internal audits that includes a traceability audit every six months that he undertakes alternately with one of his Persons Designated (PDs). On this occasion, the DI undertakes the audit and begins by writing down the unique identifier for a cadaver which is being used for teaching and traces this back to the donor records. The DI looks through the paper records to check for the following (this is not an exhaustive list):

- *evidence that the death certificate has been signed*
- *evidence that the death has been registered*
- *the date the cadaver was received*
- *what body parts can be retained (if any)*
- *the retention period (if applicable)*
- *any specific burial / cremation / disposal requests*
- *whether the relatives want to attend a thanksgiving service*

Governance and quality systems standards (GQ1–GQ7) *(continued)*

The DI then checks the electronic records to ensure that they reflect the paper records and starts another audit by recording the unique identifier of one anatomical specimen, in this case a spleen. As with the audit of the cadaver, he traces the specimen to the paper and electronic records and this time, in addition to the checklist above, the DI checks specifically for the following:

- whether the records for the spleen detail the correct location of the container and the correct container identifier*
- whether there is any indication in the records that the spleen should not have been retained*

After undertaking the audits, the DI randomly selects a paper record and then a different electronic record and goes to the corresponding cadaver and specimen in storage. In addition, he identifies the records of two cadavers that have been cremated and checks that the date of cremation and any memorial ceremony is recorded.

The DI noted some discrepancies which he rectified and he will address by briefing his PD and ensuring that he updates the SOPs to reflect the changes needed. In addition, the DI has scheduled a further traceability audit in three months time where he will repeat the process and check practices against the updated SOPs.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

41. Staff working under HTA anatomy licences are generally from three main groups: bequeathal staff, technical staff and teaching staff. The training required for each group of individuals therefore differs substantially. We found that in the main, staff in all groups at licensed anatomy establishments are appropriately trained and qualified in techniques relevant to their work and have the opportunity to continuously update their skills.

Governance and quality systems standards (GQ1–GQ7) (continued)

42. Where we found this not to be the case, we offered guidance to DIs suggesting, for example, that staff working under the licence had their training and competency recorded, had the opportunity to carry out Continuing Professional Development (CPD) and enrol in courses relevant to licensable activities such as new embalming techniques.
43. Quality management is an area in need of improvement across the anatomy sector. The HTA advises that where possible, DIs invest time and resources into training a few members of staff, perhaps PDs, in the basic principles of quality management. DIs could begin with disseminating this inspection summary report so that the learning from our inspections so far can be shared. We also advise that staff complete the DI e-learning course on the HTA website: www.hta.gov.uk/licensing/designated_individuals_and_licence_holders.cfm which is designed to be accessible and helpful to anybody working under an HTA licence.

GQ4 There is a systematic and planned approach to the management of records

44. Anatomy establishments keep a number of records demonstrating consent, the tracking of the body and its parts from the point of entry to burial or cremation, as well as an inventory of specimens. Evidence from phase 1 and phase 2 inspections demonstrated that all establishments effectively managed their records which were stored securely.

GQ5 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

45. During inspection, the HTA seeks to assure itself that bodies, specimens and former anatomical specimens are traceable from consent through to burial or disposal and each body and subsequent parts are individually labelled with a unique identifier.

Governance and quality systems standards (GQ1–GQ7) (continued)

46. All establishments demonstrated that they had effective coding and records systems showing, for example, whether bodies were allocated for anatomical examination and whether parts had been retained and if so, where they were stored. Following one audit, we advised a DI to label the container storing the prosections as well as its lid with the unique body number and table number, and to label the boxes of multiple prosections with the unique identifiers of the content.

GQ6 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

47. Adverse event reporting is a key aspect of quality management. Examples of adverse events in the anatomy sector, excluding those relating to health and safety, include events that could have led or indeed did lead to theft or damage to the integrity of bodies and specimens, unauthorised access to the dissecting room, the misidentification of a body or to the wishes of the donor not being upheld.
48. We found that all but one establishment had systems in place for reporting and managing adverse events. In this case of non-compliance we added a condition to the licences which required the DI to implement a formal system to ensure that all complaints and adverse events were reported and logged, and that records included a description of corrective and preventative measures taken.

GQ7 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

49. Risk assessments are linked to adverse events as mitigating the risk, for example, of the misidentification of a body or unauthorised access to the dissecting room, means that it is less likely that adverse events attributable to those risks will occur.

Governance and quality systems standards (GQ1–GQ7) (continued)

50. Evidence gathered during phase 1 demonstrated that establishments had good systems in place for managing risk. However, following interviews with DIs and PDs and evidence gathered during phase 2 inspections, we found that some DIs are not entirely clear about what risks, other than those related to health and safety, need to be assessed. We advise DIs to identify the critical processes from consent through to the receipt, storage and then burial or disposal of bodies and specimens and to undertake a risk assessment at each stage. DIs should also consider implementing any control measures needed, for example, an SOP and / or checklist and create a schedule of risk assessments which could be referred to in a quality manual.
51. We applied a condition to the licences at one establishment following the site visit. This required the DI to update risk assessments and control of substances hazardous to health (COSHH) assessments, as flammable embalming fluid was not kept in a fire-resistant store.
52. DIs are advised to consider reviewing the risk assessments in their establishments to ensure they focus on all processes as well as on health and safety matters.
53. **Scenario** – as with the scenario supporting our findings on quality management and audit, this scenario draws on good practice that we have seen at phase 1 and 2 of the inspection process. It also reflects the advice and guidance that inspectors have offered during site visits.

A DI asked a PD to update the risk assessments covering all practices and processes taking place under the licence. The PD informs the DI that although mandatory health and safety assessments have taken place, not all practices and processes have been risk-assessed. The DI advises the PD to start at the beginning of the donation process and end with burial or cremation.

Governance and quality systems standards (GQ1–GQ7) (continued)

The PD takes each step in turn and assesses the risks relevant to that part of the process. Some of the risks that the PD identifies are:

- some cadavers have been received before receipt of all necessary paperwork*
- the unique identifier is generated manually so there is risk of duplication;*
- electronic microchips are used but they are easily detached from the body*
- some staff work on their own for prolonged periods of time*
- there is no formal agreement in place with funeral directors*

Following completion of the risk assessments, the PD devises an action plan which sets out how each risk will be mitigated. The DI approves this plan which is then shared with the rest of the staff working under the HTA licences. The PD then amends all related SOPs and attaches the updated risk assessments to them. The DI makes sure that the risk assessments are reviewed on a regular basis.

Premises, facilities and equipment standards (PFE1–PFE5)

Key findings

54. The premises, facilities and equipment at anatomy establishments are generally of a reasonable to good standard and despite limited resources, bodies and specimens are stored in suitable environments and equipment is well maintained. We applied two conditions to licences and issued eight items of advice and guidance.

PFE1 The premises are fit for purpose

55. The size and nature of licensed anatomy premises differ across the sector, as does the number of cadavers received each year. We considered that the premises at all establishments, including those we visited, were fit for purpose.
56. The HTA understands that it is not unusual for staff at anatomy establishments to work alone. Where we found this to be the case, we advised the DI to consider providing a panic alarm so that lone workers have access to help in the event of an emergency. This may be something other DIs can consider for their staff.
57. In one instance, we advised the DI to consider implementing recordable CCTV on entry to the dissecting room, as this would assist in tracing which students and staff members were on the premises at any given time.

Premises, facilities and equipment standards (PFE1–PFE5) (continued)

PFE2 Environmental controls are in place to avoid potential contamination

58. Across the anatomy sector, the health and safety of staff is considered to be of great importance. It therefore follows that environmental controls are in place and all but one establishment complied with this standard. On site, we highlighted a few areas for improvement including the relocation of a metal storage cabinet from under an emergency shower and ending the practice of using wood blocks for positioning the body during the embalming process, as blocks made from impervious material would be easier to clean and reduce the risk of infection to staff.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records

59. Bodies used for anatomical examination are embalmed for long-term use and not generally stored in temperature-controlled environments. Smaller anatomical specimens are often stored in boxes or tubs; others are potted and stored in glass containers. We considered that the storage for bodies and specimens at all establishments was suitable.

Premises, facilities and equipment standards (PFE1–PFE5) (continued)

PFE4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to its destination

60. Bodies are transported to and from licensed establishments by funeral directors, usually under some form of Service Level Agreement (SLA). Where we found this not to be the case on site, we advised the DI to consider implementing one. Where third parties supply the cadavers, formal agreements ordinarily set out the responsibility for transport. As can be seen in consent standard C1, we required some DIs to implement agreements with third party providers to ensure that the consent was obtained in accordance with the HT Act and codes of practice. Similarly, we required one DI to ensure that the formal agreement set out the responsibility for the transportation of cadavers.
61. The HT Act allows for specimens to be loaned to non-licensed establishments providing this happens under the authority of the DI and are returned to the licensed establishment. The HTA provides a model loan form that we expect establishments to tailor accordingly. We advised one DI to review the current form that is used to loan specimens in order to include their signature, so that the HTA can be assured that the loan is under their supervision. It is mandatory that there are systems in place to ensure that specimens are always returned to the licensed establishment. The HTA advises establishments to undertake audits at least annually to make sure this is the case. The HTA code of practice on Anatomical examination includes a section detailing the requirements for loan arrangements.

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

62. The equipment used by establishments differs across the sector. Techniques also differ, particularly in terms of how bodies are embalmed. Nevertheless we found no major deficiencies.

Disposal standards (D1–D2)

Key findings

63. Across the anatomy sector, the management of cadaver burial or cremation is handled sensitively in accordance with the wishes of the donor or relatives. Compliance with the disposal standards across the anatomy sector was high. We applied two conditions to licences but did not issue any advice and guidance.

D1 There is a clear and sensitive policy for disposing of body parts and tissue

64. Depending on the wishes of the deceased or their relatives, bodies are either buried or cremated following their use for anatomical examination. Many establishments hold annual memorial or thanksgiving ceremonies as a mark of respect to the donors and their families. Body parts are often retained to be used for teaching. We found that all but one of the 45 licensed anatomy establishments had a policy or procedure in place covering the burial or cremation process.

D2 The reasons for disposal and the methods used are carefully documented.

65. Cadavers are buried or cremated on completion of the anatomical examination. The HTA is aware of the overall national shortage of cadavers and in this context, recognises the general commitment of technical staff to uphold the wishes of donors by preserving bodies for use for anatomical examination for as long as is viable.

Appendix 1:

Licensing and inspection processes

The HTA defines inspection as a process encompassing desk-based review, site visit assessment and analysis of relevant written, numerical, verbal and visual information to evaluate an establishment's compliance with expected standards. Desk-based reviews are described as phase 1 inspections and site visit assessments are described as phase 2 inspections. Phase 2 inspections are primarily used to gather information that can only be gathered by going on site. Both phase 1 and phase 2 inspections lead to licensing decisions.

Phase 1 inspections

Phase 1 inspections involve a thorough analysis and evaluation of the compliance report licence application submitted by the proposed LH and the proposed DI. This information is often supplemented with additional verbal or written information requested by HTA during telephone interviews and email exchanges with the proposed DI and / or LH, as part of the process. Phase 1 inspections lead to a licensing decision including whether to grant or refuse a licence.

Phase 2 inspections

Phase 2 site visit inspections are conducted based on the findings from a phase 1 inspection plus any other relevant information. The focus during a phase 2 inspection is on reviewing an establishment's operational policies and procedures, inspection of its premises and scrutiny of its practices. This involves interviews with a range of staff at the premises. This allows the HTA to follow up any areas of non-compliance, and evaluate progress against any licence conditions imposed at a phase 1 inspection.

A risk-based approach to inspections

The HTA targets phase 2 site visit inspections at those establishments deemed to be at highest risk both across sectors and within sectors (please note, as described above, all establishments have a mandatory phase 1 desk based inspection). Risk is context-specific and we refer here to the risk of regulatory non-compliance.

Appendix 1:

Licensing and inspection processes (continued)

We also conduct phase 2 site visit inspections at low-risk establishments. This is to assess the validity of the risk assessment process we use when scheduling inspections, which helps ensure that the assessment of risk is appropriate. The phase 2 inspections also allow the HTA to gather knowledge from high performing (low-risk) organisations and to share learning about this across the sector.

Occasionally, the HTA may carry out a 'reactive' inspection. This may be announced or unannounced. The decision to carry out a reactive inspection is usually based upon receipt of information about an establishment that raises concerns regarding regulatory compliance.

The role of the HTA in making licensing decisions

The HTA has a statutory responsibility to make judgements about the suitability of the proposed Designated Individual (DI), Licence Holder (LH), premises and practices in relation to the licensed activities. This means that during a phase 1 inspection and before issuing a licence, the HTA must be satisfied that the applicant is a suitable person or entity to be the LH, and that the premises are suitable for the activities to be authorised.

The HTA must also be satisfied that the DI is a suitable person and can supervise the activities authorised by the licence. This requires the DI to have a sound knowledge and understanding of licensed activities and associated operational procedures. The HTA helps DIs to understand their statutory responsibilities by providing advice and guidance via meetings, email, workshops and training events, as well as the DI e-learning course: www.hta.gov.uk/licensing/designated_individuals_and_licence_holders.cfm and a guide for DIs and LHs: www.hta.gov.uk/licensing/designated_individuals_and_licence_holders/dls_under_the_ht_act.cfm

Although a DI's statutory responsibilities cannot be delegated, operational responsibility can be: the HTA advises DIs to identify key staff within each licensed area that can act as Persons Designated (PD) under the licence to support them in fulfilling their statutory role.

Appendix 1:

Licensing and inspection processes (continued)

To enable the HTA to make effective judgements, we have developed standards with input from the professionals working in the sectors we license. These licensing standards form the basis of the compliance report licence application and are in four broad themes:

- consent
- governance and quality systems
- premises, facilities and equipment
- disposal

Compliance with the HTA standards is assessed through inspection, using a four-point numerical scale.

1 = standard not met

2 = standard partially met

3 = standard almost met

4 = standard fully met or exceeded

Where the inspection process identifies that a standard is not being met, formal advice and guidance may be offered or formal regulatory action may be taken where the non-compliance triggers the HTA's power to vary a licence. There are several different types of regulatory action which may be considered by the HTA: variation of licences through, for example, the imposition of additional conditions; issue of Special Directions; suspension of a licence or revocation of a licence. In the vast majority of cases, the HTA will take regulatory action by varying a licence to impose additional conditions. Additional conditions are time-bound and DIs are required to inform the HTA when they have taken appropriate action to comply with them. The HTA then assesses this information to decide whether the establishment has met the condition or whether further regulatory action should be taken.

Complex regulatory issues are normally brought before a Regulatory Action Panel (RAP), to ensure that all relevant considerations are taken into account and that a fair, proportionate and justifiable licensing decision is made. RAPs are normally chaired by the Director of Regulation and consist of a Head of Regulation, a Legal Advisor and the Regulation Manager responsible for making the licensing decision.

Appendix 1:

Licensing and inspection processes (continued)

The difference between advice and guidance and licence conditions

The HTA works as a compliance-based regulator, which means we place a strong emphasis on the value of providing advice and guidance to professionals working within the sector. This is so that they understand regulatory requirements and are better equipped to meet standards. Where enforcement is necessary, we aim to make evidence-based, justifiable and proportionate decisions. Phase 2 inspections also lead to advice and guidance from the HTA on how the establishment can improve its practices.

The HTA provides verbal and written advice and guidance in a wide variety of ways. We provide a great deal of written advice and guidance during phase 2 site visit inspections in the spirit of continuous quality improvement, and these recommendations are for the DI and staff to consider to make improvements to their systems, processes and practices. Whilst these are not statutory requirements, any advice and guidance made by the HTA is carefully considered and is intended to help establishments reflect on their practice and make improvements.

Regulatory sanctions imposed on an establishment (most frequently in the form of licence conditions) hold statutory weight and failure by the DI to comply with a licence condition is a breach of the DI's statutory duties, which gives HTA the power to revoke a licence.

Appendix 2:

List of establishments which received an HTA phase 2 inspection

- Department of Anatomy and Developmental Biology, University College London
- Institute of Life Science Education, University of Leeds
- Medical Sciences Division, University of Oxford
- University of Bristol

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