HTA
Human Tissue Authority

Anatomy sector review March 2015

A summary of HTA inspection findings, advice and learning 2010-14

Executive summary

In May 2014, the HTA completed its first cycle of site visit inspections for all establishments licensed in the anatomy sector. This summary report collates the findings of the inspections of these establishments and provides an analysis of the trends and themes to facilitate further improvements in this sector. We hope this report will be useful to people working in the sector, and of wider interest to members of the public and other parties.

In the period November 2010 to May 2014, we licensed 36 anatomy establishments and conducted 24 site visit inspections. We identified a total of 23 shortfalls against the HTA licensing standards and offered 152 items of advice. This summary report shows that HTA-licensed anatomy establishments generally met the HTA's licensing standards. We found that the main areas requiring improvement in this sector are in governance and quality systems, and this report summarises the key learning points relevant to improving practices in this area.

The notable levels of regulatory compliance seen in anatomy establishments reflect the widely-held respect for the gift of body donation and the genuine commitment to upholding the dignity of the deceased.

Introduction

1. The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, patient treatment, post-mortem examination, anatomical examination, and public display. We license establishments that carry out these activities, and inspect them to make sure legal requirements are met. We also give approval for organ and bone marrow donations from living people.

2. Anatomical examination is a scheduled purpose in the Human Tissue Act 2004 (the HT Act). We license 36 establishments in our anatomy sector, making it one of the smallest of the sectors we regulate. In addition to anatomical examination, many facilities store and use human tissue for other purposes, such as surgical training and research.

3. In May 2014, the HTA completed its first cycle of site visit inspections for all establishments licensed in the anatomy sector. This report contains a summary of the inspection findings and main trends in compliance with the HTA licensing standards since the last summary report for this sector in 2010. To encourage reflection on practice, this report also provides examples of how the HTA licensing standards can be met and highlights areas of good practice.

4. We conduct site visit inspections of licensed establishments to assess their compliance with our licensing requirements and to offer advice on how they can improve. As the anatomy sector has been considered to be of low regulatory risk, inspections of anatomy establishments have been scheduled across longer periods of time than in other sectors.

5. Site visit inspections comprise a visual inspection of the premises and facilities, meetings with staff and a review of policies and procedures. Establishments are assessed against a set of minimum standards relating to the four overarching standards of: consent (C); governance and quality systems (GQ); premises, facilities and equipment (PFE), and; disposal (D).

6. The findings from site visit inspections are presented in inspection reports. Since November 2010, we have produced exception-based inspection reports, where only those HTA standards that have not been met are detailed in the reports. Inspection reports also include advice and good practice. All inspection reports since November 2010 are published on the HTA website in order for us to be transparent about the regulatory action we take and to provide opportunities for learning across the sector.

7. Where a HTA licensing standard has not been met, a shortfall is identified and classified as ‘critical’, ‘major’ or ‘minor’. We work with establishments to address shortfalls through corrective and preventative action plans. The timeframe for completion of corrective and preventative actions depends on the classification of the shortfall. Critical shortfalls are the most serious and are expected to be addressed immediately. Major shortfalls require corrective and preventative actions to be completed within one to two months of the final report being issued. Minor shortfalls are expected to be addressed within three to four months of the final report being issued. Further information about our inspection processes can be found in Appendix 1.

8. Where a HTA standard is fully met, but we identify an area of practice that could be further improved, we provide advice to the establishment and include this in the inspection report. Our inspection reports also highlight areas identified during inspection to represent good practice. By publishing examples good practice in our inspection reports and in summary publications, we aim to share people’s successes and provide support to others.

Overview of the anatomy sector and inspection findings

9. In May 2014, we completed our first cycle of inspections of all establishments licensed in the anatomy sector. This report includes an analysis of the shortfalls, advice, and good practice identified during inspections undertaken from November 2010 to May 2014. Eleven inspections conducted prior to November 2010 were excluded from this review because the reporting of inspection findings changed after this time. Previous summary reports for this sector provide an overview of our inspection findings prior to the change.

10. At the time of writing this report, there are 36 establishments licensed in the anatomy sector. These comprise 29 standalone premises and seven hub sites associated with a total of 14 satellite sites. Altogether, this means that there are currently 50 sites licensed in this sector.

11. Between November 2010 and May 2014, we undertook site visit inspections of 24 establishments in this sector. A list of the establishments inspected in this period and summarised in this report is provided in Appendix 2. A total of 23 shortfalls were identified during these site visit inspections. One of these shortfalls was classified as 'major', and this was against HTA standard PFE3, which relates to the storage of bodies. Many of the minor shortfalls related to establishments not having formal documents in place to manage processes, audits and risk assessments. In addition to supporting the development of corrective actions to address these shortfalls, we also provided a number of items of advice to help to improve these areas. Common areas of advice are presented in this summary report, along with a number of examples of good practices which were highlighted.

12. The anatomy sector has been shown to generally meet the HTA's licensing requirements. The findings set out in this report confirm the anatomy sector's status as a low-risk, high-compliance sector.

Inspection findings (November 2010 – May 2014) findings

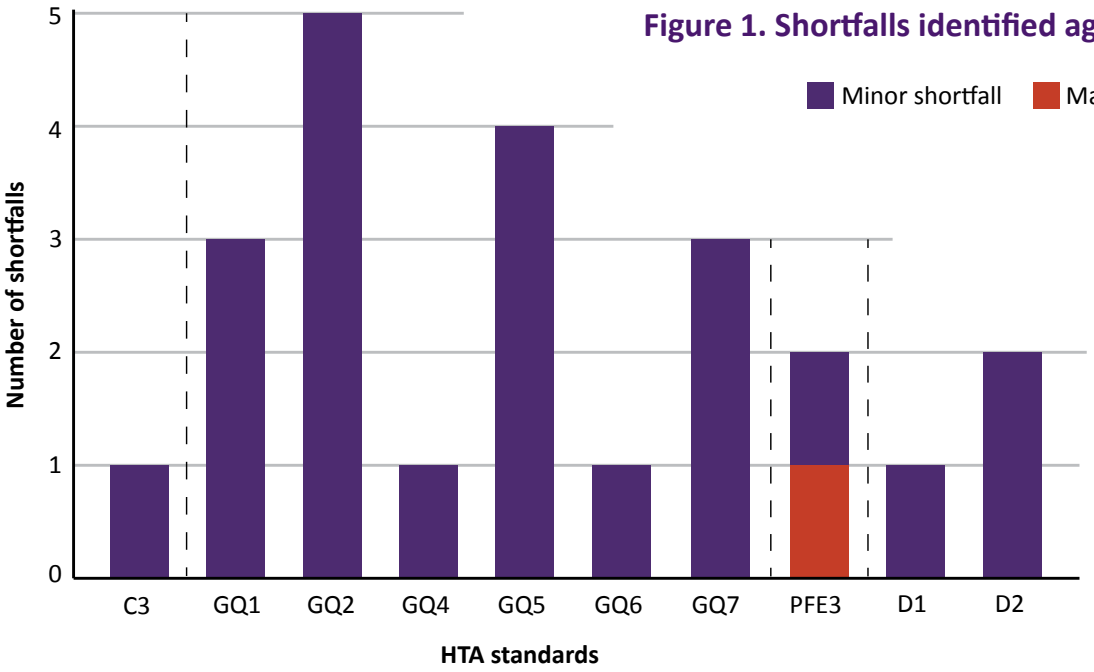
Shortfalls

13. A total of 23 shortfalls were identified during the 24 inspections of anatomy establishments conducted from November 2010 to May 2014. These shortfalls were identified across nine establishments, with no shortfalls identified at the remaining 15 establishments inspected during this period.

14. Only one major shortfall was identified and this was against HTA standard PFE3 (Figure 1; red bar). This standard relates to facilities for the storage of bodies and is discussed in more detail later in this report.

15. Twenty-two minor shortfalls were identified during these inspections and these were against a range of HTA standards (Figure 1; purple bars). Seventeen of these shortfalls were against the governance and quality systems (GQ) standards and these were mostly against standards GQ1, GQ2, GQ5 and GQ7. Compliance with these standards is discussed in more detail later in this report.

Figure 1. Shortfalls identified against HTA standards

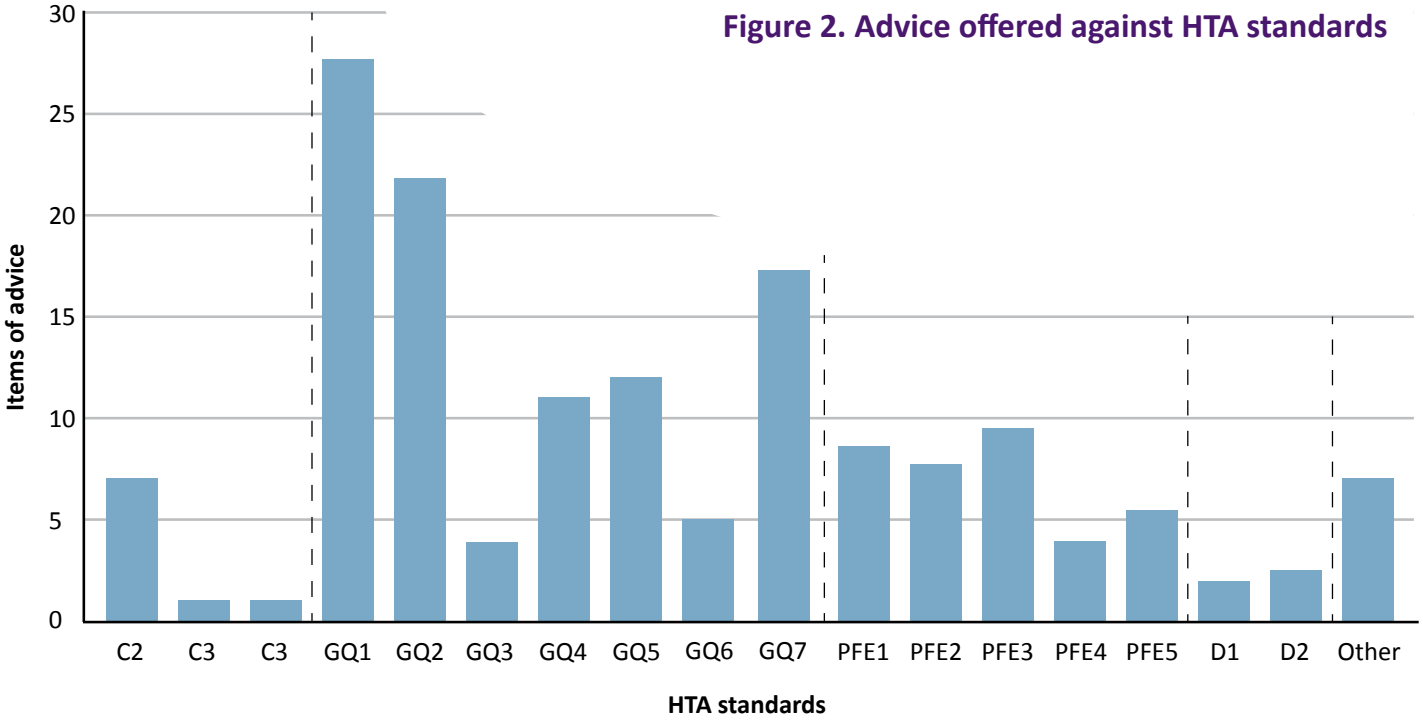


Advice

16. A total of 152 items of advice were offered in the 24 inspection reports. The majority of advice related to the GQ standards, in particular to standards GQ1, GQ2, GQ4, GQ5 and GQ7 (Figure 2).

17. This is to be expected given that the majority of shortfalls were issued against a similar set of GQ standards. In particular, the greatest number of advice items was provided for standards GQ1 and GQ2, which relate to quality management systems. Much of this advice concerned the requirement for documenting formal procedures for all licensed practices. The key areas of advice for each of the HTA standards are described later in this report.

Figure 2. Advice offered against HTA standards



Compliance with HTA standards

19. Overall, establishments in the anatomy sector were found to be compliant with the HTA's standards. The key areas commonly identified as requiring improvement are outlined here for each of the standards, alongside our advice and learning points. We have also highlighted practical examples to demonstrate compliance with the standards and particular examples of good practice.

Consent (C) standards

Key findings

20. The vast majority of anatomy establishments demonstrated that they met the HTA standards on consent, confirming that consent is obtained in accordance with the HT Act and our codes of practice. A number of establishments have strong systems in place to support respectful and robust consent processes.

21. Only one minor shortfall was identified against the consent standards, and this was for standard C3. Compliance with this standard is outlined below.

22. We offered nine items of advice for improving consent practices, and these were mostly for standard C1. A number of establishments obtain specimens from other organisations, either from centralised donation centres or imported from organisations from outside of England, Wales and Northern Ireland. Where establishments obtain specimens only from other organisations, consent standards C2 and C3, relating to consent processes and training, are not directly applicable. In such cases, the establishments must assure themselves that the consent obtained by these organisations is in accordance with the regulatory requirements.

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

23. Although there were no shortfalls identified for standard C1, seven of the nine items of advice concerning consent related to this standard.

24. Our advice commonly related to the agreements in place with third parties supplying specimens for training. Four establishments were advised to review these agreements to ensure that the information provided to donors about the use, retention and disposal of specimens was in accordance with practices that the establishment intended to undertake.

25. One establishment seeking consent was advised to review their consent forms and the information provided to donors in order to ensure that these accurately reflected practices intended to be undertaken at the establishment.

Advice and learning

26. We have published model consent forms for body donation for anatomical examination, which can be found on our website. A number of establishments are now using these model consent forms as the basis for their own consent forms.

27. Although taking photographs of human material is not covered by the HT Act, if an establishment intends to allow photographs to be taken of specimens to facilitate training, it is good practice for this to be included in the consent information. A number of establishments include this in their bequeathal process and strictly control any photography in accordance with the consent obtained. Particular examples of good practice were noted where establishments

had implemented colour-coded systems to label human material, or the dissection tables on which they were placed, to indicate where consent for photographs has been given.

28. Where establishments receive specimens from other organisations, they must have agreements in place to ensure that consent is obtained in accordance with the regulatory requirements. These agreements should be reviewed periodically to ensure that material is used, handled, stored, transported, and disposed of in accordance with the donors' wishes and the consent given.

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

29. Many establishments seeking consent in this sector use a bequeathal booklet to provide information to potential donors. A number of establishments have bequeathal staff who manage the consent process. The handling of consent processes in this sector was highlighted as an area of good practice during many of our inspections.

Advice and learning

30. Establishments should ensure that the consent process provides full information to donors in a variety of suitable formats. The fonts used in bequeathal booklets and consent forms should be clear and of an appropriate size to be easily read.

31. In addition to bequeathal booklets used by a number of establishments, some establishments use checklists when talking to donors about the body donation process. This helps to ensure that donors are fully informed during the consent process and provides a record of the information discussed with potential donors.

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

32. The quality of staff training was highlighted as an area of good practice at a number of anatomy establishments. Many establishments encourage staff to undertake training and career development programmes. A number of individuals were commended for their detailed knowledge of the HT Act and the codes of practice and their practical knowledge of anatomical examination.

33. We identified one minor shortfall against consent standard C3, which related to an establishment which did not have records to evidence up to date consent training. We also provided advice to this establishment on the requirements of consent training and the records needed to evidence training. This establishment also did not have a formal standard operating procedure (SOP) detailing the consent process and this was identified as a shortfall against standard GQ1. The establishment was advised that the associated SOP should be a clear and accurate representation of the procedure, ideally written in a step wise fashion to enable any member of staff to follow the procedure to completion.

Advice and learning

34. Staff seeking consent should undergo suitable training, including the requirements of the HT Act 2004 and reference to the relevant codes of practice. Attendance at consent training and periodic refresher training should be recorded and a list of staff trained to seek consent should be maintained. As an on-going source of assurance, establishments can audit consent documentation to ensure that the person who sought consent was appropriately trained.

Governance and quality systems (GQ) standards

Key findings

35. Many establishments had good quality management systems that were managed effectively by a range of dedicated staff including technical staff, lecturers and bequeathal secretaries. However, the majority of the shortfalls identified during our inspections were against the GQ standards. This reflects the findings of our previous summary reports for this sector, where compliance with the GQ standards has been found to be weaker compared with the other groups of standards.

36. The most common areas of governance and quality systems requiring improvement concerned the documentation of policies and procedures (GQ1), quality management and audit (GQ2), traceability of specimens (GQ5) and risk assessments (GQ7).

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

37. Three minor shortfalls were identified against GQ1, relating to inspections of three separate establishments. While these establishments had procedures in place for licensable activities, formal documentation of these procedures was underdeveloped. Some policies and procedures had not been formally documented and some SOPs did not describe procedures in sufficient detail.

38. The highest number of advice items related to standard GQ1. This advice mostly related to the need to ensure that all practices are documented and that documents contain sufficient procedural details.

39. A number of establishments were advised to improve the standard of their overall governance processes, for example by improving governance meetings. This often comprised advice to document governance meetings and introduce standing agenda items for licensed activities.

Advice and learning

40. Formal documentation of procedures helps to establish approved, consistent and reproducible ways of undertaking licensed activities. People undertaking the processes should be involved in developing the SOPs to ensure that the written procedures reflect actual practices. Regular review of SOPs will help to prevent incremental departure from written processes with passing time and allow establishments to identify improvements. Establishments should introduce a system to record that staff have read and understood SOPs.

41. Overall governance processes should be supported by regular meetings with staff at the establishment who are engaged in licensed activities. Formal meetings should be minuted and the actions should be noted and followed up. Documented minutes of meetings should be distributed to all relevant staff to help to ensure that they are aware of all important information relating to licensed activities at the establishment.

42. Some establishments have also set up meetings with Designated Individuals (DIs) at other establishments. This can facilitate staff learning and provide a forum for the discussion of good practices. Links with other DIs can also facilitate audit processes, as discussed below.

GQ2 There is a documented system of quality management and audit

43. There were five minor shortfalls identified against standard GQ2, relating to inspections of four establishments. Four of these shortfalls related to the need for formal audits

and documentation of completed audits. In one case, although the establishment had completed formal audits, it had not documented a number of interim checks and follow-up actions from these audits. A number of establishments were advised to strengthen their audit processes and their associated documentation, including corrective and preventative actions.

44. The fifth minor shortfall identified against this standard was due to an underdeveloped quality management system. This establishment did not have a formal framework of policies and procedures covering licensed activities. Two other establishments were also advised on how to improve their quality management systems.

Advice and learning

45. To develop and implement a formal document control system, establishments are advised to include elements in their documents that allow for review and change control, such as issue numbers and dates, authors and reviewers.

46. Establishments are encouraged to have an over-arching quality document which provides an overview of the establishment's main purpose, organisation and structure and approach to governance and quality. This document should be accessible to all staff involved in licensed activities. A formal quality management framework helps to establish minimum expectations for governance and quality systems, and facilitates continuous improvement.

47. A documented schedule of audits should be in place at each establishment. Vertical audits of records and specimens will allow the establishment to assure itself that specimens and records are fully traceable from consent to disposal. Audits should ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. All audit findings and related corrective and preventative actions should be recorded to allow the establishment to demonstrate compliance with HTA standards and follow-up outstanding actions.

48. Audit processes can benefit from being undertaken by a person who is not normally involved in the activity at the establishment: a 'fresh eyes' view. A notable example of good practice in this sector was demonstrated at an establishment where an external peer audit had been conducted by the DI of another establishment licensed in the anatomy sector.

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

49. No shortfalls were identified against standard GQ3 and only four establishments required advice to improve their programmes for staff training. Advice relating to staff training for seeking consent is outlined above in relation to standard C3.

50. The provision of staff training opportunities was highlighted as an area of good practice at a number of establishments. It was frequently noted that staff were motivated and knowledgeable.

Advice and learning

51. Training and induction packages help to ensure that staff are fully trained on all policies and procedures. Establishments should ensure that training and development plans are in place and that these are reviewed periodically.

52. Staff should be encouraged to attend professional meetings and training events to ensure that they keep abreast of good practices in their areas of expertise.

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

53. One minor shortfall was identified against standard GQ4, where an establishment did not have a documented procedure for the retention of records. Nine other establishments were advised to improve their management of records. This included advice to ensure that document control practices reflect those outlined in documented procedures; for example, to ensure that documents were reviewed in line with the timeframe described in the SOP for document control.

Advice and learning

54. Documented procedures for the creation, amendment, retention and destruction of records are required to help to ensure that records are maintained appropriately. Document control SOPs should detail the frequency of document review required to ensure that documents are regularly reviewed and updated as necessary. A centralised system for the storage of records can help to ensure that records are regularly backed-up.

55. Regular audits of records to check for completeness, legibility and accuracy help to ensure that records are maintained appropriately. Establishments should make sure that use of correction fluid is avoided to ensure that full traceability of written records is maintained.

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

56. Establishments in this sector generally demonstrated that they had robust systems to trace human material. Four minor shortfalls against GQ5 were identified. These findings were highlighted as a result of difficulties in tracing material during audit trails undertaken by HTA inspectors. Three of these shortfalls related to a lack of suitable coding or labelling to facilitate traceability. For example, individual prosections did not have unique identifiers meaning that they could not accurately be traced to the donor records and inventory of specimens.

57. For one establishment, discrepancies were identified in the audit trail for material transferred between the hub and the satellite site. Advice on the transfer of specimens between hub and satellite sites and arrangements for loaning specimens to other sites is outlined below.

58. The other shortfall against standard GQ5 related to an establishment where improved documentation was required to ensure full traceability of specimens at all stages following the donation. This shortfall was identified during the HTA's audit and related to an undocumented deviation from the establishment's agreed procedures.

Advice and learning

59. A register of donors and specimens should be maintained which should allow all specimens to be identified and traced through to the consent documentation.

60. Establishments should ensure that traceability is maintained for specimens transported between sites. Records of loan arrangements should be kept and include important details, including: the location where specimens will be stored whilst on loan, dates that specimens have left and arrived at each site, and the condition of specimens. We have produced model loan arrangement templates which are available on our website. A SOP documenting the process of arrangements for the transport and loan of specimens will help to ensure that the traceability of specimens is maintained.

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

61. One minor shortfall was identified against standard GQ6. This was at an establishment where the systems and processes for dealing with adverse incidents were underdeveloped and there was no formal SOP for managing adverse incidents.

Advice and learning

62. Clearly assigning responsibilities for incident management is important. As the DI is responsible for licensed activities at the establishment, there should be a process in place to allow them to be made aware of adverse events so that proper investigation and reporting can take place. There should be an adverse incident SOP detailing how adverse incidents are logged, reported, addressed and monitored.

63. Although there is currently no requirement for establishments in the anatomy sector to report adverse incidents to the HTA, if a DI has concerns about an adverse event, they are encouraged to contact us for further advice.

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

64. Three minor shortfalls were identified against standard GQ7 and these were due to a lack of, or insufficiently detailed, risk assessments at three establishments. A large number of items of advice were offered in relation to improving risk assessments. The key advice points for documenting risk assessments are outlined here.

Advice and learning

65. Establishments may tend to focus risk assessment on health and safety practices. While these are important, DIs should also assess the risks associated with licensed activities.

66. Risk assessments should include the risks relating to the premises, practices and procedures connected with licensed activities, including:

    - loss of or damage to specimens;
    - loss of traceability;
    - receiving specimens without appropriate consent documentation;
    - storage of anatomical specimens and contingency arrangements;
    - transport of specimens to and from the establishment, and;
    - security arrangements.

67. Documented risk assessments should include an evaluation of the level of the risk and, where appropriate, the mitigating actions identified and the level of residual risk remaining.

68. Risk assessments should be reviewed periodically and the actions to mitigate risks updated as necessary. By documenting risk assessments, staff are made aware of identified risks, which helps to inform the development of procedures and relevant documentation.

Premises, facilities and equipment (PFE) standards

Key findings

69. A number of areas of good practice were identified in relation to the premises, facilities and equipment at anatomy establishments. Establishments often demonstrated comprehensive security arrangements to ensure that access to different areas of the premises is well managed and controlled. Particular strengths were also highlighted in the measures in place to ensure the respectful use of facilities by students in order to maintain the dignity of the deceased.

70. There were two shortfalls identified against the PFE standards. These were both against standard PFE3 and were due to arrangements for the storage of bodies. PFE3 shortfalls are described in detail below.

PFE1 The premises are fit for purpose

71. Although the majority of establishments demonstrated satisfactory premises, advice relating to standard PFE1 was given to seven establishments. This often related to the need to ensure that the risks relating to security, storage and donor confidentiality are documented and updated.

Advice and learning

72. Establishments should periodically review risk assessments of premises, facilities and equipment. This should ideally include an audit of the premises and equipment in order to identify areas requiring rolling maintenance, refurbishment or upgrade. This will help to ensure that remedial actions are implemented in a timely manner so that the premises, facilities and equipment remain fit for purpose.

73. Establishments are expected to have policies in place to review and maintain the safety of staff, visitors and students. Since anatomy establishments frequently host teaching sessions, registers of visitors, including all students, should be completed. Many establishments also restrict the number of students present during teaching sessions in the anatomy suite to ensure that anatomical examination can be well supervised and conducted safely and efficiently.

74. A number of anatomy establishments have implemented particularly good measures to ensure that the safety of visitors and the dignity of the deceased is maintained. Notable examples of this include comprehensive induction packages for students, detailing the requirements of the HT Act and the HTA's codes of practice. Some establishments have also had a local code of conduct, which students are required to acknowledge before entering the anatomy suite. These measures help to ensure that the dignity of the deceased is always upheld.

PFE2 Environmental controls are in place to avoid potential contamination

75. In general, appropriate environmental controls and cleaning practices were in place although documentation of these practices required improvement at some establishments. A number of establishments were advised to update SOPs to include the need for cleaning and maintenance to be recorded.

Advice and learning

76. Establishments should document cleaning and decontamination procedures in formal SOPs. Records should also be kept of when cleaning and decontamination occurs.

77. Where formaldehyde is in use, environmental levels should be monitored and controlled to maintain safe working conditions for staff. Establishments should ensure that equipment used for environmental monitoring is maintained and calibrated in accordance with recommendations and technical instructions.

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

78. There was one major shortfall identified against standard PFE3. This related to the storage of fresh frozen bodies in a facility within an anatomy dissection suite. This arrangement was not considered to afford sufficient control of access and dignity of the deceased. This arrangement differed from that for the embalmed bodies at this establishment and actions were required to address this.

79. A minor shortfall for standard PFE3 was identified at a different establishment. This related to monitoring of the conditions of storage of prosections which was not formally documented or recorded. A number of establishments were advised to improve their documentation of temperature monitoring.

Advice and learning

80. Documented temperature monitoring allows establishments to easily visualise and identify when temperatures are out of range. It can also demonstrate temperature trends, to identify when storage conditions may be deteriorating and to alert staff to developing equipment failure. Temperature alarms should be manually challenged periodically to ensure that they are operating as expected.

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

81. Establishments generally had well-embedded processes for the transfer of specimens between sites. A number of establishments were commended on their good working relationships with contracted funeral directors, local registrars and local crematoria. This good communication can help staff to manage the relevant procedures efficiently and with minimum delay, to the benefit of relatives.

82. Some establishments were advised to improve the documentation of specimen transfer. The key learning points from this are outlined in relation to the traceability of specimens (standard GQ5).

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

83. The standard of equipment in anatomy establishments was largely found to be appropriate. Some specific items of advice were given to further ensure that all equipment used for licensed activities is fit for purpose and appropriately maintained. In addition to advice on the calibration of environmental monitoring equipment (standard PFE2), advice for ensuring that equipment is appropriate for use is summarised below.

Advice and learning

84. All equipment within anatomy suites should be appropriate for use and maintained. Establishments should periodically review the equipment, fabric and finish of the key areas in which licensed activities are undertaken. Porous materials should be avoided or suitably sealed in order to minimise the risk of contamination and to facilitate effective cleaning. Establishments should also relocate extraneous items which are not needed to support activities in these areas in order to further facilitate cleaning.

Disposal standards (D1–D2)

Key findings

85. We found that establishments within this sector often strive to ensure that the dignity of the deceased is given paramount importance. Many establishments hold committal, memorial or thanksgiving ceremonies as a mark of respect to the donors and their families.

86. Across the anatomy sector, the management of burial or cremation of anatomical specimens is handled sensitively in accordance with the donor's wishes. Compliance with the HTA's disposal standards across this sector was high and only three minor shortfalls were identified in relation to disposal.

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

87. The one minor shortfall identified against standard DI related to one establishment that did not have a documented policy or procedure for disposal of specimens. Although the establishment had not previously disposed of any relevant material, a documented policy needed to be developed to ensure that, should any specimens be disposed of, this would be undertaken in accordance with the donor's wishes.

Advice and learning

88. Establishments should have documented arrangements for disposal. The disposal process should be in accordance with the donor's wishes.

89. A number of establishments demonstrated particular examples of good practice to ensure that anatomical specimens are handled sensitively, through the whole donation process, including their disposal; for example, the use of dedicated bowls in the dissection facilities to ensure that cuttings from each dissection are collected appropriately for sensitive disposal with the related body.

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

90. There were two minor shortfalls identified against standard D2. These related to the records of disposal which did not adequately record the dates of disposal. Two other establishments were advised to ensure that the details of disposal recorded by staff are standardised.

Advice and learning

91. Establishments should carefully document disposal. Supporting procedures should detail the requirements for recording the details of disposal, including the date, method and reason. Records of disposal should be kept in order to provide a complete audit trail from donation through to disposal.

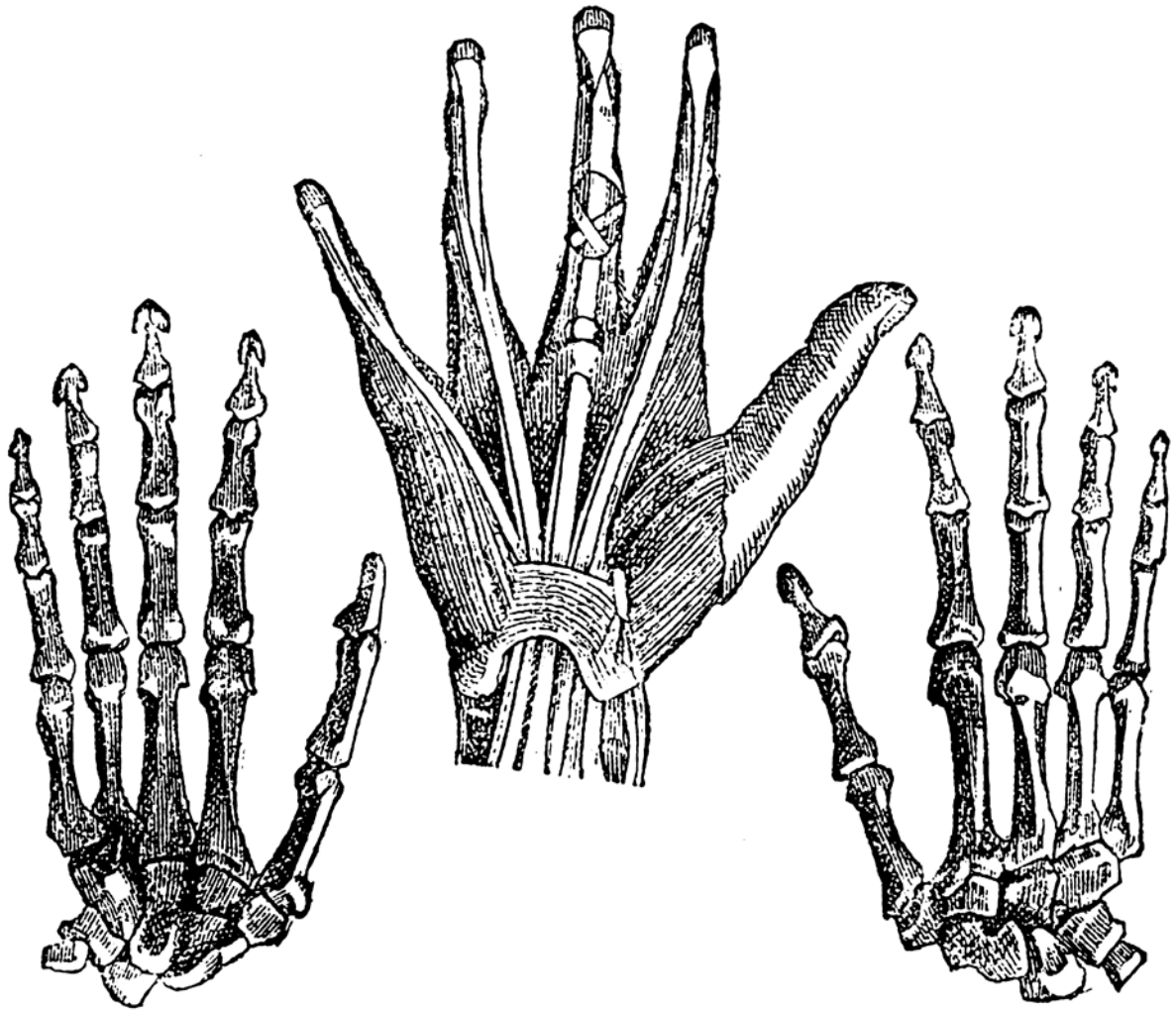
Appendix 1: Inspection processes

Site visit inspections

As one of our regulatory functions, we carry out inspections of licensed establishments. During an inspection, we meet with staff, view premises and facilities, and review policies and procedures.

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that: other staff working under the licence are suitable; suitable practices are used when carrying out the activity, and; the conditions of the licence are met. We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal. We assess establishments against these minimum standards during site visit inspections.



Shortfalls in meeting the licensing standards

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

Critical shortfall

A shortfall is classified as 'critical' where it poses a significant risk to human safety and/or dignity, or is a breach of the HT Act or associated Directions. A combination of several major shortfalls, none of which is critical on its own, may together constitute a critical shortfall.

A critical shortfall may result in one or more of the following actions:

1. A notice of proposal being issued to revoke the licence;
2. Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented;
3. A notice of suspension of licensable activities;
4. Additional conditions being proposed;
5. Directions being issued requiring specific action to be taken straightaway.

Major shortfall

A 'major' shortfall is a non-critical shortfalls that: poses a risk to human safety and/or dignity, or; indicates a failure to carry out satisfactory procedures, or; indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or; has the potential to become a critical shortfall unless addressed. A combination of several minor shortfalls, none of which is major on its own, may together constitute a major shortfall.

In response to a major shortfall, an establishment is expected to implement corrective and preventive actions within 1-2 months of the final inspection report being issued. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

Minor shortfall

A 'minor' shortfall is which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA. In response to a minor shortfall, an establishment is expected to implement corrective and preventive actions within 3-4 months of the final report being issued.

Corrective and preventative actions

We work with establishments to address shortfalls through corrective and preventative action plans. Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventive action plan.

The timeframe for completion of corrective and preventative actions depends on the classification of the shortfall. Our inspection reports are updated to confirm when corrective and preventative actions have been completed to address all shortfalls.

Inspection reports

After every site visit inspection, we write a report documenting our findings. Since November 2010, we have produced exception-based inspection reports, where only those HTA standards that have not been met are detailed in the reports. Reports for site visit inspections which have taken place since date are published on our website.

Appendix 2: Licensed establishments in the anatomy sector

The establishments listed in Table 1 were inspected between 1 November 2010 and 31 May 2014 and were included in the summary data provided in this report.

Table 1: Establishments included in this summary report

Licence number	Licensed Premises	Satellites
12004	Barts and The London, Queen Mary's School of Medicine and Dentistry	
12005	University of East Anglia	
12022	Institute of Learning & Teaching	
12065	Cardiff School of Biosciences	
12070	Anglo-European College of Chiropractic (AECC)	
12078	Hull York Medical School (HYMS)	1. HYMS
12085	School of Life Sciences	1. School of Graduate Entry Medicine and Health 2. School of Veterinary Medicine and Science
12098	Brighton and Sussex Medical School (BSMS)	
12111	Faculty of Life Sciences	
12113	Queen's University Belfast	
12123	School of Biomedical and Health Sciences	
12130	Medical Teaching Unit	
12146	Department of Physiology, Development and Neuroscience	
12148	Anatomy and Clinical Skills	1. Durham University School for Health 2. Temporal Bone Laboratory 3. Minimally Invasive Surgery Training Facility
12161	Ear Institute	
12190	Keele University, School of Medicine (Anatomy Facility)	
12236	University of Birmingham	
12367	University of Brighton School of Health Professions	
12389	Swansea University	
12399	University of Leicester Medical School	
12546	Bangor University	1. School of Healthcare Sciences 2. School of Sport, Health and Exercise Sciences 3. School of Chemistry
12555	University of Southampton Faculty of Medicine	
12576	Smith & Nephew Surgical Skills Centre	
12603	Evelyn Cambridge Surgical Training Centre	

Establishments listed in Table 2 were inspected before 1 November 2010 and were excluded from the summary data provided in this report.

Table 2: Establishments excluded this summary report

Licence number	Licensed Premises	Satellites
12073	Department of Anatomy	
12120	UCL, Department of Anatomy & Developmental Biology	
12135	University of Bristol	
12178	University of Oxford Medical Sciences Division Medical Sciences Teaching Centre	
12235	Imperial College London	1. Burlington Danes Building 2. Department of Psychological Medicine
12279	Faculty of Medicine and Health	
12330	St George's University of London, Division of Basic Medical Sciences (Anatomy)	
12423	Royal College of Surgeons of England	
12482	University of Northumbria at Newcastle (School of Applied Sciences)	
12487	Wrightington Hospital	
12547	Minimal Access Therapy Training Unit	
30019	University Hospitals Coventry and Warwickshire NHS Trust	

Appendix 3: Additional sources of information

HTA Code of Practice 1 - Consent

HTA Code of Practice 4 - Anatomical Examination

HTA Code of Practice 5 - Disposal of human tissue

HTA model forms, including:

- Donation Model Consent Form
- Model Authorisation Form or Loan of Anatomical and Former Anatomical Specimens

HTA Policy on the import of fresh frozen bodies and body parts